

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Atezolizumab (Tecentriq®)

Roche Pharma AG

Modul 4A Anhang 4-G

Erwachsene Patienten mit NSCLC nach vollständiger Resektion und platinbasierter Chemotherapie mit hohem Risiko für ein Rezidiv und deren Tumoren eine PD L1-Expression auf $\geq 50\%$ der Tumorzellen aufweisen und kein EGFR-mutiertes oder ALK-positives NSCLC haben (siehe Abschnitt 5.1 der Fachinformation).

**Vollständige Darstellung der für das
vorliegende Dossier relevanten
Ergebnisse in unveränderter Form**

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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Wirksamkeit

Time-to-Event (TTE) Analysen

Stratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Overall Survival
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)												
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status						
All	n/a	106	100,0	10	9,4	96	90,6	NE	NE	NE	NE	NE	NE	NE	NE	103	100,0	24	23,3	79	76,7	36,4	27,8	NE	NE	NE	NE	0,0100	0,39	0,18	0,82	Convergence criterion (GCONV=1E-8) satisfied.						

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_OS_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Earliest Contributing Event to Disease Free Survival by Investigator
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)										Atezolizumab vs. Best Supportive Care (BSC)																			
		Patients				Patients with Event				Censored				Time to event						Patients				Patients with Event				Censored				Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status											
All	n/a	106	100,0	24	22,6	82	77,4	36,0	27,9	NE	NE	NE	NE	NE	NE	103	100,0	45	43,7	58	56,3	11,1	7,3	21,4	37,3	30,1	NE	0,0045	0,49	0,29	0,81	Convergence criterion (GCONV=1E-8) satisfied.											

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_DFS_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Earliest Contributing Event to Recurrence by Investigator
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)													
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status									
All	n/a	106	100,0	21	19,8	85	80,2	36,0	32,3	NE	NE	NE	NE	103	100,0	43	41,7	60	58,3	11,1	7,3	23,9	37,3	32,0	NE	0,0025	0,45	0,26	0,76	Convergence criterion (GCONV=1E-8) satisfied.									

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_RECUR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Earliest Contributing Event (Death) to Disease Free Survival by Investigator
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)												
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status						
All	n/a	106	100,0	3	2,8	103	97,2			NE	NE	NE	NE	NE	NE	103	100,0	2	1,9	101	98,1			NE	NE	NE	NE	NE	NE	0,7254	1,39	0,22	8,74	Convergence criterion (GCONV=1E-8) satisfied.				

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_DTHNOREC_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
 ENDPOINT: Earliest Contributing Event to Disease Free Survival by BICR
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=59)												Best Supportive Care(BSC) (N=51)												Atezolizumab vs. Best Supportive Care(BSC)												
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status								
All	n/a	59	100,0	15	25,4	44	74,6	27,4	23,5	NE	NE	38,5	NE	51	100,0	22	43,1	29	56,9	12,0	4,3	29,6	50,3	23,9	NE	0,1844	0,62	0,31	1,26	Convergence criterion (GCONV=1E-8) satisfied.								

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_DFSO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
 ENDPOINT: Earliest Contributing Event to Recurrence by BICR
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=59)												Best Supportive Care(BSC) (N=51)										Atezolizumab vs. Best Supportive Care(BSC)																			
		Patients				Patients with Event				Censored				Time to event						Patients				Patients with Event				Censored				Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status													
All	n/a	59	100,0	11	18,6	48	81,4	NE	24,3	NE	NE	NE	NE	51	100,0	18	35,3	33	64,7	12,0	4,3	50,3	50,3	35,7	NE	0,1636	0,58	0,26	1,26	Convergence criterion (GCONV=1E-8) satisfied.													

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_RECURO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
 ENDPOINT: Earliest Contributing Event (Death) to Disease Free Survival by BICR
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=59)												Best Supportive Care(BSC) (N=51)												Atezolizumab vs. Best Supportive Care(BSC)												
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status						
All	n/a	59	100,0	4	6,8	55	93,2			NE	38,5	NE	NE	NE	NE	51	100,0	4	7,8	47	92,2			NE	33,4	NE	NE	NE	NE	0,8814	0,88	0,16	4,81	Convergence criterion (GCONV=1E-8) satisfied.				

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_tte_str_DTHNORECO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Wirksamkeit

Time-to-Event (TTE) Analysen

Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Efficacy)

		Atezolizumab (N=106)											Best Supportive Care(BSC) (N=103)											Atezolizumab vs. Best Supportive Care(BSC)							
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio			Interaction Test			
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	106	100,0	10	9,4	96	90,6	NE	NE	NE	NE	NE	NE	103	100,0	24	23,3	79	76,7	36,4	27,8	NE	NE	NE	NE	0,0045	0,36	0,17	0,75	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	84	79,2	7	8,3	77	91,7	NE	NE	NE	NE	NE	NE	73	70,9	18	24,7	55	75,3	33,4	26,1	NE	NE	NE	NE	0,0038	0,30	0,12	0,71	Convergence criterion (GCONV=1E-8) satisfied.	0,3991
	Female	22	20,8	3	13,6	19	86,4	NE	25,7	NE	NE	NE	NE	30	29,1	6	20,0	24	80,0	39,2	24,6	NE	NE	NE	NE	0,5125	0,63	0,16	2,53	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	65	61,3	5	7,7	60	92,3	NE	NE	NE	NE	NE	NE	62	60,2	14	22,6	48	77,4	NE	26,0	NE	NE	NE	NE	0,0176	0,31	0,11	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,6765
	>= 65	41	38,7	5	12,2	36	87,8	NE	36,7	NE	NE	NE	NE	41	39,8	10	24,4	31	75,6	36,4	26,2	NE	NE	39,2	NE	0,1126	0,43	0,15	1,26	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	30	28,3	1	3,3	29	96,7	NE	NE	NE	NE	NE	NE	24	23,3	3	12,5	21	87,5	NE	29,8	NE	NE	NE	NE	0,2062	0,26	0,03	2,48	Convergence criterion (GCONV=1E-8) satisfied.	0,7489
	Europe and Middle East	66	62,3	8	12,1	58	87,9	NE	36,7	NE	NE	NE	NE	68	66,0	20	29,4	48	70,6	27,8	22,5	NE	NE	NE	NE	0,0113	0,36	0,16	0,82	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,4	1	10,0	9	90,0	NE	38,5	NE	NE	NE	NE	11	10,7	1	9,1	10	90,9	NE	36,4	NE	NE	NE	NE	0,8084	0,71	0,04	11,79	Convergence criterion (GCONV=1E-8) satisfied.	
Race/Ethnicity	White	71	67,0	7	9,9	64	90,1	NE	NE	NE	NE	NE	NE	77	74,8	19	24,7	58	75,3	33,4	24,6	NE	NE	NE	NE	0,0139	0,35	0,15	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,5684
	Asian	31	29,2	1	3,2	30	96,8	NE	NE	NE	NE	NE	NE	24	23,3	4	16,7	20	83,3	39,2	36,4	NE	NE	39,2	NE	0,1066	0,20	0,02	1,77	Convergence criterion (GCONV=1E-8) satisfied.	
	Others	2	1,9	1	50,0	1	50,0	38,5	38,5	NE	NE	38,5	NE	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	2	1,9	1	50,0	1	50,0	33,1	NE	NE	33,1	NE	NE	2	1,9	1	50,0	1	50,0	26,2	26,2	NE	NE	26,2	NE	0,8084	1,41	0,08	23,57	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)												Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio				Interaction Test p-value (likelihood ratio)
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	
Tumor stage per eCRF	IIA	31	29,2	4	12,9	27	87,1	NE	36,7	NE	NE	NE	NE	33	32,0	6	18,2	27	81,8	NE	28,6	NE	NE	NE	NE	0,4739	0,63	0,18	2,24	Convergence criterion (GCONV=1E-8) satisfied.	0,5187
	IIB	27	25,5	2	7,4	25	92,6	NE	NE	NE	NE	NE	NE	15	14,6	2	13,3	13	86,7	NE	30,8	NE	NE	NE	NE	0,5441	0,55	0,08	3,91	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	48	45,3	4	8,3	44	91,7	NE	NE	NE	NE	NE	NE	55	53,4	16	29,1	39	70,9	27,8	22,5	NE	NE	NE	NE	0,0082	0,25	0,08	0,76	Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy Regimen before Randomization	Cisplatin/Vinorelbine	44	41,5	4	9,1	40	90,9	NE	38,5	NE	NE	NE	NE	36	35,0	8	22,2	28	77,8	39,2	30,8	NE	NE	NE	NE	0,1348	0,41	0,12	1,37	Convergence criterion (GCONV=1E-8) satisfied.	0,7334
	Cisplatin/Docetaxel	13	12,3	1	7,7	12	92,3	NE	NE	NE	NE	NE	NE	19	18,4	7	36,8	12	63,2	26,1	13,5	NE	NE	26,2	NE	0,0492	0,16	0,02	1,30	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Gemcitabine	20	18,9	3	15,0	17	85,0	NE	31,0	NE	NE	NE	NE	16	15,5	3	18,8	13	81,3	NE	18,8	NE	NE	NE	NE	0,5357	0,61	0,12	3,02	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Pemetrexed	29	27,4	2	6,9	27	93,1	NE	NE	NE	NE	NE	NE	32	31,1	6	18,8	26	81,3	NE	22,2	NE	NE	NE	NE	0,1896	0,36	0,07	1,78	Convergence criterion (GCONV=1E-8) satisfied.	
Histology per eCRF	Squamous	47	44,3	7	14,9	40	85,1	NE	36,7	NE	NE	NE	NE	45	43,7	10	22,2	35	77,8	39,2	26,1	NE	NE	NE	NE	0,2600	0,58	0,22	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,1464
	Non-Squamous	59	55,7	3	5,1	56	94,9	NE	NE	NE	NE	NE	NE	58	56,3	14	24,1	44	75,9	36,4	22,2	NE	NE	NE	NE	0,0040	0,19	0,06	0,67	Convergence criterion (GCONV=1E-8) satisfied.	
Smoking History	Never	11	10,4	1	9,1	10	90,9	NE	16,9	NE	NE	NE	NE	10	9,7	2	20,0	8	80,0	NE	22,5	NE	NE	NE	NE	0,4831	0,43	0,04	4,79	Convergence criterion (GCONV=1E-8) satisfied.	0,1332
	Previous	79	74,5	5	6,3	74	93,7	NE	NE	NE	NE	NE	NE	72	69,9	18	25,0	54	75,0	36,4	26,1	NE	NE	NE	NE	0,0012	0,22	0,08	0,60	Convergence criterion (GCONV=1E-8) satisfied.	
	Current	16	15,1	4	25,0	12	75,0	36,7	25,7	NE	NE	36,7	NE	21	20,4	4	19,0	17	81,0	NE	23,6	NE	NE	NE	NE	0,7366	1,27	0,32	5,07	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG Status	0	66	62,3	5	7,6	61	92,4	NE	NE	NE	NE	NE	NE	53	51,5	11	20,8	42	79,2	36,4	29,8	NE	NE	NE	NE	0,0240	0,32	0,11	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,6512

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)												Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	1 and 2 combined	40	37,7	5	12,5	35	87,5	NE	36,7	NE	NE	NE	NE	50	48,5	13	26,0	37	74,0	28,6	22,5	NE	NE	NE	NE	0,1142	0,44	0,16	1,25	Convergence criterion (GCONV=1E-8) satisfied.	
Regional Lymph Node Stage (pN)	N0	30	28,3	4	13,3	26	86,7	NE	36,7	NE	NE	NE	NE	20	19,4	3	15,0	17	85,0	NE	39,2	NE	NE	NE	NE	0,9535	0,96	0,21	4,28	Convergence criterion (GCONV=1E-8) satisfied.	0,3460
	N1	39	36,8	2	5,1	37	94,9	NE	38,5	NE	NE	NE	NE	43	41,7	8	18,6	35	81,4	NE	28,6	NE	NE	NE	NE	0,0534	0,24	0,05	1,15	Convergence criterion (GCONV=1E-8) satisfied.	
	N2	37	34,9	4	10,8	33	89,2	NE	NE	NE	NE	NE	NE	40	38,8	13	32,5	27	67,5	26,2	22,2	NE	NE	36,4	NE	0,0180	0,28	0,09	0,86	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Earliest Contributing Event to Disease Free Survival by Investigator
 MODEL: Unstratified Analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test	
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
All	n/a	106	100,0	24	22,6	82	77,4	36,0	27,9	NE	NE	NE	NE	103	100,0	45	43,7	58	56,3	11,1	7,3	21,4	37,3	30,1	NE	0,0007	0,43	0,26	0,71	Convergence criterion (GCONV=1E-8) satisfied.		
Sex per eCRF	Male	84	79,2	19	22,6	65	77,4	36,0	27,9	NE	NE	36,7	NE	73	70,9	27	37,0	46	63,0	12,0	7,3	33,4	NE	34,2	NE	0,0364	0,54	0,30	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,2268	
	Female	22	20,8	5	22,7	17	77,3	32,3	4,7	NE	NE	NE	NE	30	29,1	18	60,0	12	40,0	9,0	4,5	17,8	30,1	10,2	37,3	0,0063	0,27	0,10	0,73	Convergence criterion (GCONV=1E-8) satisfied.		
Age at Randomization	< 65	65	61,3	15	23,1	50	76,9	35,3	27,9	NE	NE	36,1	NE	62	60,2	27	43,5	35	56,5	12,2	8,0	32,0	35,7	32,0	NE	0,0142	0,46	0,25	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,7092	
	>= 65	41	38,7	9	22,0	32	78,0	36,7	24,0	NE	NE	36,7	NE	41	39,8	18	43,9	23	56,1	7,3	4,2	19,4	NE	17,2	NE	0,0190	0,40	0,18	0,88	Convergence criterion (GCONV=1E-8) satisfied.		
Geographic Region	Asia Pacific and Australia	30	28,3	5	16,7	25	83,3	36,0	14,7	NE	NE	NE	NE	24	23,3	10	41,7	14	58,3	9,0	4,2	NE	NE	11,1	NE	0,0312	0,32	0,11	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,7384	
	Europe and Middle East	66	62,3	16	24,2	50	75,8	35,3	27,9	NE	NE	36,7	NE	68	66,0	30	44,1	38	55,9	12,0	4,5	30,1	37,3	30,1	NE	0,0087	0,45	0,25	0,83	Convergence criterion (GCONV=1E-8) satisfied.		
	North America	10	9,4	3	30,0	7	70,0	11,8	2,3	NE	NE	11,8	NE	11	10,7	5	45,5	6	54,5	17,2	7,3	NE	35,7	17,2	NE	0,5585	0,65	0,16	2,75	Convergence criterion (GCONV=1E-8) satisfied.		
Race/Ethnicity	White	71	67,0	16	22,5	55	77,5	35,3	27,9	NE	NE	36,7	NE	77	74,8	33	42,9	44	57,1	12,2	8,0	30,1	37,3	32,0	NE	0,0055	0,44	0,24	0,80	Convergence criterion (GCONV=1E-8) satisfied.	0,7981	
	Asian	31	29,2	6	19,4	25	80,6	36,0	12,0	NE	NE	36,0	NE	24	23,3	10	41,7	14	58,3	9,0	4,2	NE	NE	11,1	NE	0,0531	0,38	0,14	1,05	Convergence criterion (GCONV=1E-8) satisfied.		
	Others	2	1,9	1	50,0	1	50,0	11,8	11,8	NE	NE	11,8	NE	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	2	1,9	1	50,0	1	50,0	11,1	11,1	NE	NE	11,1	NE	2	1,9	2	100,0	0	0,0	4,2	4,2	NE	4,3	4,2	NE	0,0896	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.		

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)													
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli hood ratio)				
Tumor stage per eCRF	IIA	31	29,2	4	12,9	27	87,1			36,7	36,7	NE	NE	36,7	NE	33	32,0	11	33,3	22	66,7			29,0	10,0	NE	NE	30,1	NE	0,0480	0,33	0,11	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,3059				
	IIB	27	25,5	9	33,3	18	66,7			30,1	24,0	36,1	36,0	32,3	NE	15	14,6	6	40,0	9	60,0			10,2	4,0	NE	NE	32,0	NE	0,9331	0,96	0,34	2,71	Convergence criterion (GCONV=1E-8) satisfied.					
	IIIA	48	45,3	11	22,9	37	77,1			32,3	12,0	NE	NE	NE	NE	55	53,4	28	50,9	27	49,1			8,0	4,5	17,2	33,4	17,2	NE	0,0032	0,36	0,18	0,73	Convergence criterion (GCONV=1E-8) satisfied.					
Chemotherapy Regimen before Randomization	Cisplatin/Vinorelbine	44	41,5	6	13,6	38	86,4			NE	36,0	NE	NE	NE	NE	36	35,0	17	47,2	19	52,8			14,3	4,0	32,0	34,2	29,7	NE	0,0019	0,25	0,10	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,2766				
	Cisplatin/Docetaxel	13	12,3	3	23,1	10	76,9			35,3	18,1	NE	NE	35,3	NE	19	18,4	8	42,1	11	57,9			4,5	3,8	NE	37,3	8,0	NE	0,2469	0,46	0,12	1,76	Convergence criterion (GCONV=1E-8) satisfied.					
	Cisplatin/Gemcitabine	20	18,9	7	35,0	13	65,0			32,3	24,3	36,7	36,7	32,3	NE	16	15,5	4	25,0	12	75,0			35,3	8,0	NE	NE	35,3	NE	0,9937	1,00	0,29	3,42	Convergence criterion (GCONV=1E-8) satisfied.					
	Cisplatin/Femetrexed	29	27,4	8	27,6	21	72,4			24,0	11,8	NE	NE	NE	NE	32	31,1	16	50,0	16	50,0			10,2	4,7	21,4	35,7	13,3	NE	0,0742	0,47	0,20	1,10	Convergence criterion (GCONV=1E-8) satisfied.					
Histology per eCRF	Squamous	47	44,3	12	25,5	35	74,5			32,3	25,1	NE	36,7	36,1	NE	45	43,7	17	37,8	28	62,2			12,0	7,3	33,4	NE	32,0	NE	0,1728	0,60	0,29	1,26	Convergence criterion (GCONV=1E-8) satisfied.	0,2748				
	Non-Squamous	59	55,7	12	20,3	47	79,7			36,0	14,7	NE	NE	NE	NE	58	56,3	28	48,3	30	51,7			9,6	4,2	19,4	35,7	17,8	NE	0,0014	0,35	0,18	0,69	Convergence criterion (GCONV=1E-8) satisfied.					
Smoking History	Never	11	10,4	4	36,4	7	63,6			32,3	3,9	NE	35,3	32,3	NE	10	9,7	5	50,0	5	50,0			12,2	9,0	NE	37,3	12,2	NE	0,5491	0,67	0,18	2,53	Convergence criterion (GCONV=1E-8) satisfied.	0,2038				
	Previous	79	74,5	15	19,0	64	81,0			36,1	32,3	NE	NE	NE	NE	72	69,9	34	47,2	38	52,8			8,0	4,3	17,8	35,3	19,4	NE	0,0001	0,32	0,18	0,60	Convergence criterion (GCONV=1E-8) satisfied.					
	Current	16	15,1	5	31,3	11	68,8			30,1	25,1	NE	36,7	30,1	NE	21	20,4	6	28,6	15	71,4			23,9	16,5	NE	NE	34,2	NE	0,9435	0,96	0,29	3,15	Convergence criterion (GCONV=1E-8) satisfied.					
ECOG Status	0	66	62,3	14	21,2	52	78,8			35,3	24,3	NE	NE	NE	NE	53	51,5	24	45,3	29	54,7			10,2	4,5	29,0	35,3	23,9	NE	0,0024	0,37	0,19	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,4509				
	1 and 2 combined	40	37,7	10	25,0	30	75,0			32,3	25,1	NE	36,7	36,0	NE	50	48,5	21	42,0	29	58,0			12,1	7,3	32,0	NE	30,1	NE	0,1037	0,54	0,25	1,15	Convergence criterion (GCONV=1E-8) satisfied.					

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care(BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Regional Lymph Node Stage (pN)	N0	30	28,3	9	30,0	21	70,0	32,3	25,1	36,7	36,1	35,3	NE	20	19,4	6	30,0	14	70,0	21,1	4,0	NE	NE	32,0	NE	0,9888	0,99	0,35	2,80	Convergence criterion (GCONV=1E-8) satisfied.	0,1900
	N1	39	36,8	5	12,8	34	87,2	NE	27,9	NE	NE	NE	NE	43	41,7	15	34,9	28	65,1	29,0	4,3	NE	NE	33,4	NE	0,0245	0,33	0,12	0,91	Convergence criterion (GCONV=1E-8) satisfied.	
	N2	37	34,9	10	27,0	27	73,0	24,3	12,0	NE	NE	NE	NE	40	38,8	24	60,0	16	40,0	8,0	4,7	13,3	19,4	11,1	37,3	0,0022	0,33	0,16	0,70	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

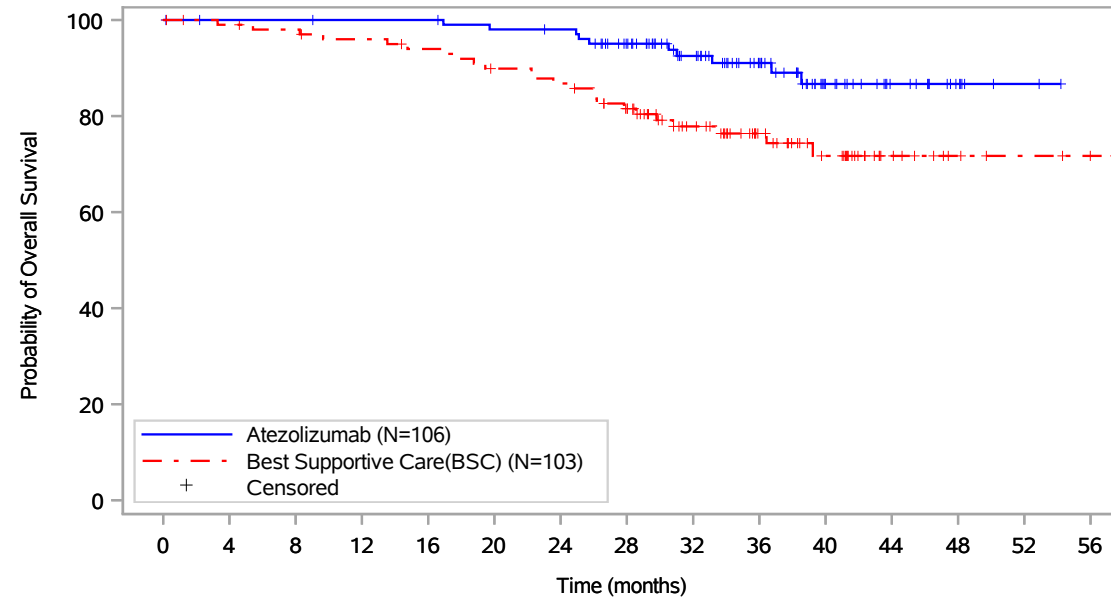
Wirksamkeit

KM Plots

Stratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Overall Survival
STUDY: GO29527



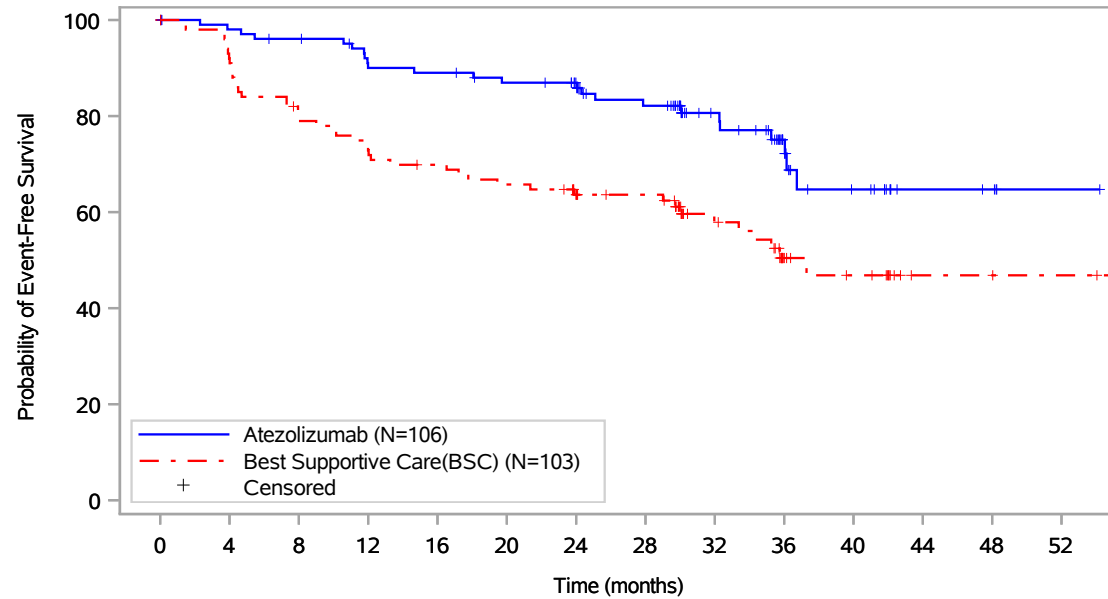
Patients at risk															
Atezolizumab (N=106)	106	104	104	103	103	100	99	88	69	50	26	15	7	2	NE
Best Supportive Care(BSC) (N=103)	103	100	98	95	92	87	84	75	56	39	26	11	5	3	1
Patients censored															
Atezolizumab (N=106)	0	2	2	3	3	4	5	13	30	48	70	81	89	94	NE
Best Supportive Care(BSC) (N=103)	0	2	3	4	5	6	6	10	26	42	53	68	74	76	78

Clinical cut-off: 21JAN2021

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 13DEC2021 16:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Earliest Contributing Event to Disease Free Survival by Investigator
STUDY: GO29527



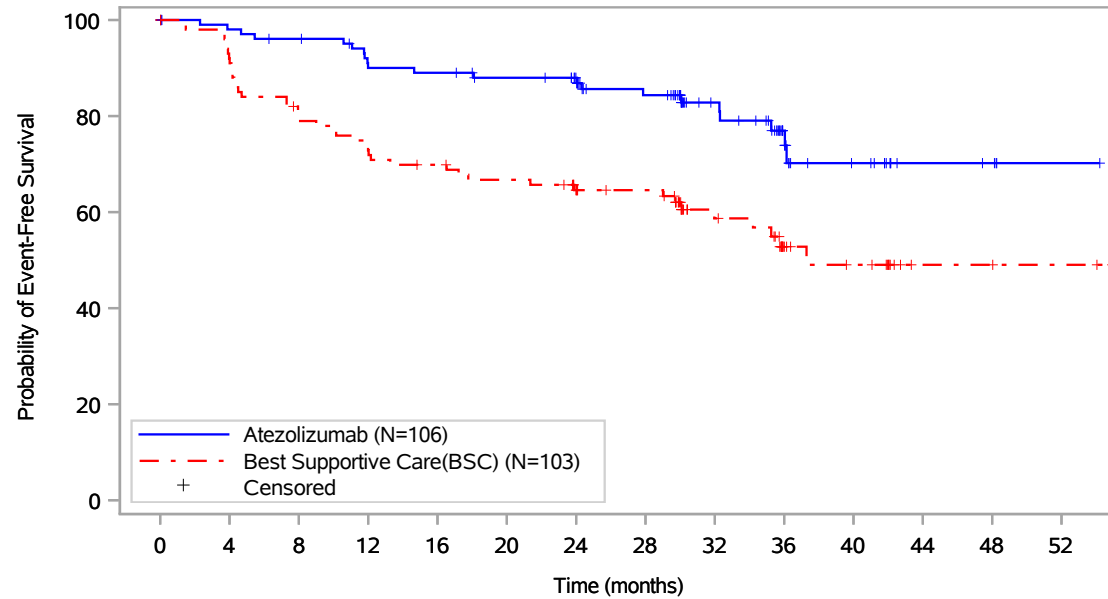
Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=106)		106	100	97	89	88	84	78	66	45	26	14	5	4	1
Best Supportive Care(BSC) (N=103)		103	92	78	72	68	64	57	52	33	17	12	3	3	2
Patients censored		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=106)		0	4	5	7	7	9	15	23	43	59	68	77	78	81
Best Supportive Care(BSC) (N=103)		0	3	4	4	5	5	10	15	30	42	46	55	55	56

Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Earliest Contributing Event to Recurrence by Investigator
STUDY: GO29527



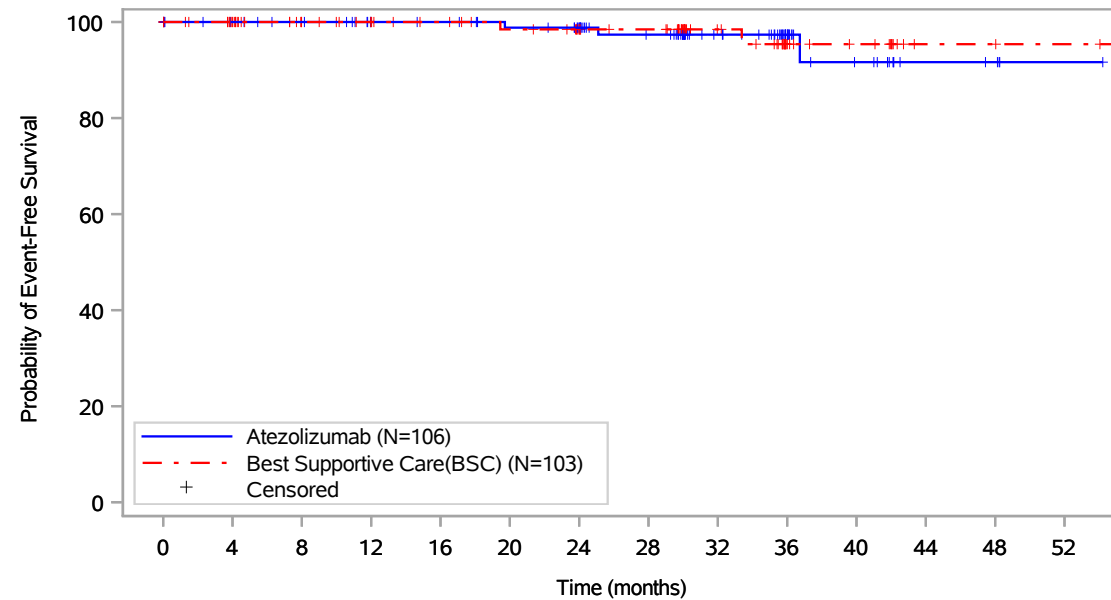
Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=106)		106	100	97	89	88	84	78	66	44	25	14	5	4	1
Best Supportive Care(BSC) (N=103)		103	92	78	72	68	64	57	52	32	17	12	3	3	2
Patients censored		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=106)		0	4	5	7	7	10	16	25	46	62	71	80	81	84
Best Supportive Care(BSC) (N=103)		0	3	4	4	5	6	11	16	32	44	48	57	57	58

Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Earliest Contributing Event (Death) to Disease Free Survival by Investigator
STUDY: GO29527



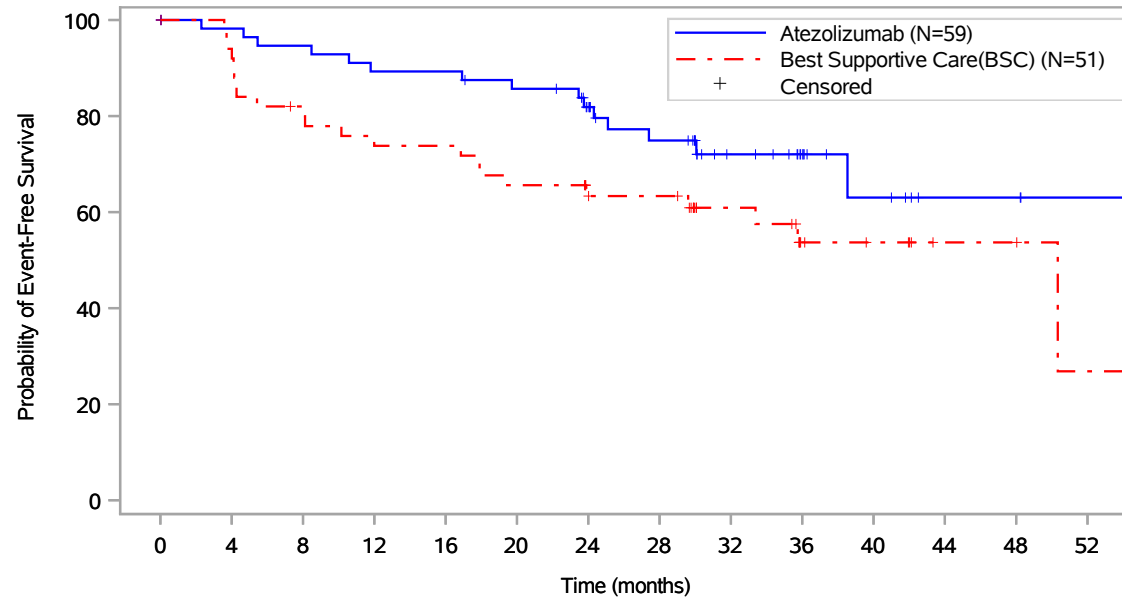
Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=106)		106	100	97	89	88	84	78	66	45	26	14	5	4	1
Best Supportive Care(BSC) (N=103)		103	92	78	72	68	64	57	52	33	17	12	3	3	2
Patients censored															
Atezolizumab (N=106)		0	6	9	17	18	21	27	38	59	78	89	98	99	102
Best Supportive Care(BSC) (N=103)		0	11	25	31	35	38	45	50	69	84	89	98	98	99

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..CE_DFS_IA/prod/output/g_km_DTHNOREC_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.pdf
 13DEC2021 16:38

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
ENDPOINT: Earliest Contributing Event to Disease Free Survival by BICR
STUDY: GO29527



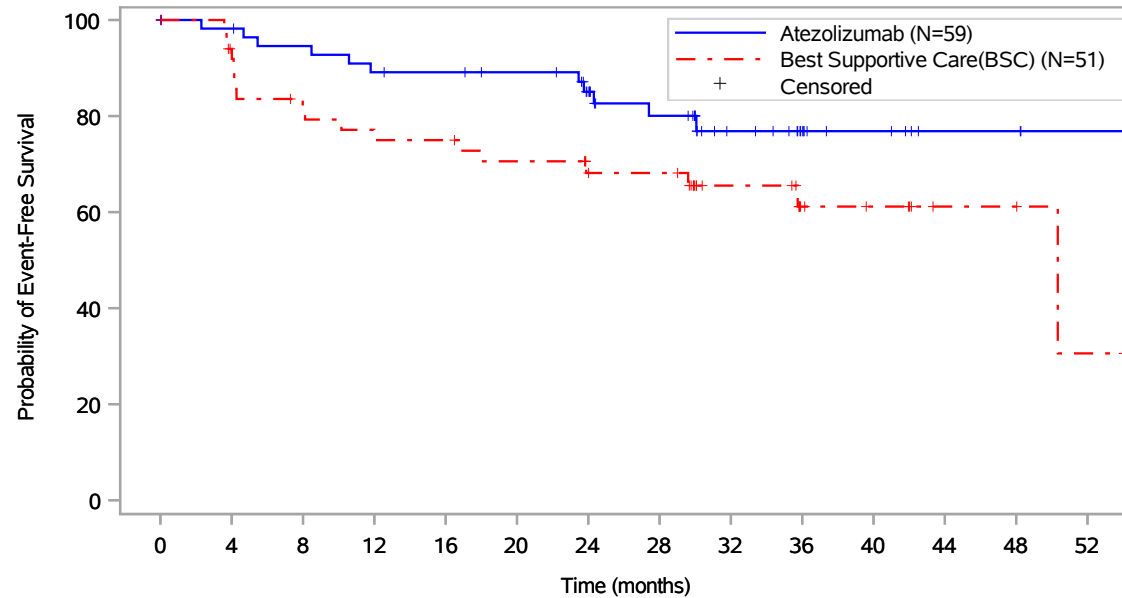
Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=59)		59	55	53	50	50	47	40	32	20	13	7	3	3	1
Best Supportive Care(BSC) (N=51)		51	47	39	36	36	32	28	27	18	9	7	3	3	1
Patients censored		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=59)		0	3	3	3	3	4	9	14	25	32	37	41	41	43
Best Supportive Care(BSC) (N=51)		0	1	2	2	2	2	5	6	14	21	23	27	27	28

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..E_DFS_IA/prod/output/g_km_DFSO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.pdf
 20JAN2022 13:13

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
ENDPOINT: Earliest Contributing Event to Recurrence by BICR
STUDY: GO29527



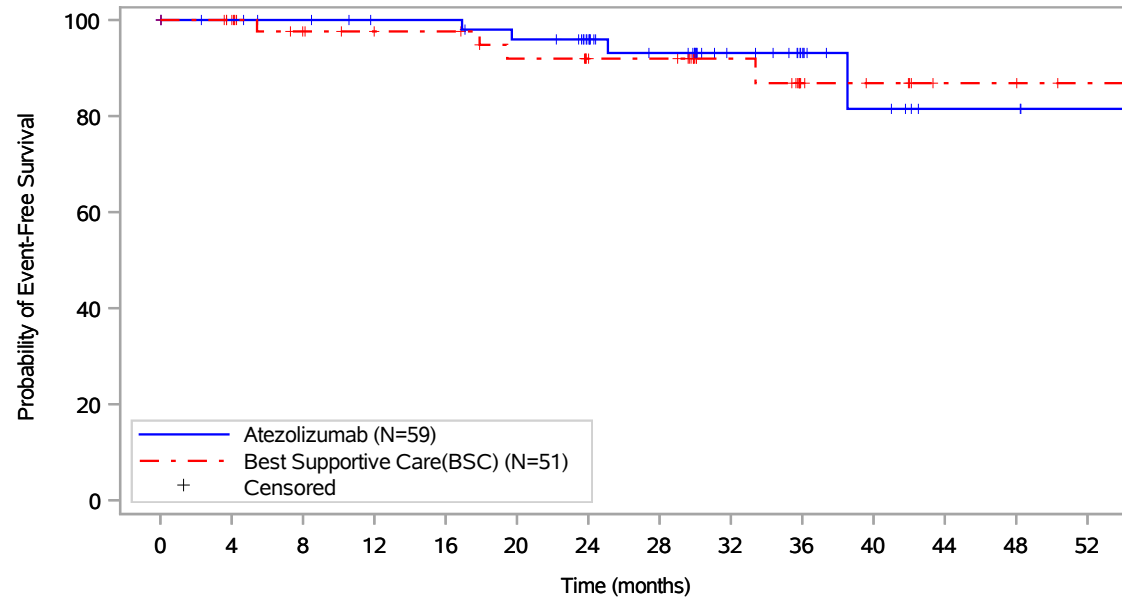
Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=59)		59	55	52	49	48	46	39	31	19	12	7	3	3	1
Best Supportive Care(BSC) (N=51)		51	45	38	35	35	32	28	27	17	9	7	3	3	1
Patients censored															
Atezolizumab (N=59)		0	3	4	4	5	7	12	18	29	36	41	45	45	47
Best Supportive Care(BSC) (N=51)		0	3	4	4	4	5	8	9	18	25	27	31	31	32

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..DFS_IA/prod/output/g_km_RECURO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.pdf
 20JAN2022 13:16

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
ENDPOINT: Earliest Contributing Event (Death) to Disease Free Survival by BICR
STUDY: GO29527



Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=59)		59	55	53	50	50	47	40	32	20	13	7	3	3	1
Best Supportive Care(BSC) (N=51)		51	47	39	36	36	32	28	27	18	9	7	3	3	1
Patients censored		0	4	8	12	16	20	24	28	32	36	40	44	48	52
Atezolizumab (N=59)		0	4	6	9	9	10	17	24	36	43	48	52	52	54
Best Supportive Care(BSC) (N=51)		0	4	11	14	14	16	20	21	30	38	40	44	44	46

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..._IA/prod/output/g_km_DTHNORECO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.pdf
 20JAN2022 13:22

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Wirksamkeit

Responder Analysen

Stratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: DFS rate by Investigator (events: Patients with DFS event)
 MODEL: Adjusted Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Dichotomous Analysis (Efficacy)

		Atezolizumab (N=106)				Best Supportive Care (BSC) (N=103)				Atezolizumab vs. Best Supportive Care (BSC)											Best Supportive Care (BSC) vs. Atezolizumab					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk			Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	106	100,0	24	22,6	103	100,0	45	43,7	0,40	Algorithm converged.	0,22	0,73	-0,188	Algorithm converged.	-0,316	-0,060	0,53	Algorithm converged.	0,35	0,81	0,0029	1,87	Algorithm converged.	1,24	2,82

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_resp_adj_DFS_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
 13DEC2021 16:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations, BICR Evaluated Patients
 ENDPOINT: DFS rate by BICR (events: Patients with DFS event)
 MODEL: Adjusted Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Dichotomous Analysis (Efficacy)

		Atezolizumab (N=59)				Best Supportive Care(BSC) (N=51)				Atezolizumab vs. Best Supportive Care(BSC)											Best Supportive Care(BSC) vs. Atezolizumab					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	59	100,0	15	25,4	51	100,0	22	43,1	0,44	Algorithm converged.	0,19	1,01	-0,177	Algorithm converged.	-0,356	0,001	0,58	Algorithm converged.	0,34	0,99	0,0474	1,73	Algorithm converged.	1,01	2,98

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_eff_resp_adj_DFSO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
 20JAN2022 13:27

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	99	95,2	5	4,8	101	100,0	70	69,3	31	30,7	<.0001	2,54	1,85	3,49	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	77	93,9	5	6,1	71	70,3	46	64,8	25	35,2	<.0001	2,77	1,90	4,04	Convergence criterion (GCONV=1E-8) satisfied.	0,5442
	Female	22	21,2	22	100,0	0	0,0	30	29,7	24	80,0	6	20,0	0,0067	2,25	1,23	4,09	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	59	92,2	5	7,8	62	61,4	40	64,5	22	35,5	<.0001	2,84	1,88	4,30	Convergence criterion (GCONV=1E-8) satisfied.	0,4042
	>= 65	40	38,5	40	100,0	0	0,0	39	38,6	30	76,9	9	23,1	0,0015	2,22	1,34	3,68	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	28	96,6	1	3,4	23	22,8	15	65,2	8	34,8	0,0012	2,80	1,47	5,33	Convergence criterion (GCONV=1E-8) satisfied.	0,8474

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	61	93,8	4	6,2	68	67,3	47	69,1	21	30,9	<.0001	2,41	1,63	3,57	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	10	100,0	0	0,0	10	9,9	8	80,0	2	20,0	0,0579	2,53	0,94	6,83	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	31	100,0	0	0,0	33	32,7	23	69,7	10	30,3	<.0001	3,19	1,79	5,70	Convergence criterion (GCONV=1E-8) satisfied.	0,6699
	IIB	27	26,0	26	96,3	1	3,7	15	14,9	12	80,0	3	20,0	0,0389	2,09	1,03	4,27	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	42	91,3	4	8,7	53	52,5	35	66,0	18	34,0	0,0001	2,38	1,50	3,77	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

01MAR2022 11:05

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	21	20,2	83	79,8	101	100,0	11	10,9	90	89,1	0,0601	1,99	0,96	4,12	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	16	19,5	66	80,5	71	70,3	6	8,5	65	91,5	0,0531	2,45	0,96	6,27	Convergence criterion (GCONV=1E-8) satisfied.	0,5461
	Female	22	21,2	5	22,7	17	77,3	30	29,7	5	16,7	25	83,3	0,5220	1,50	0,43	5,17	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	13	20,3	51	79,7	62	61,4	9	14,5	53	85,5	0,3555	1,49	0,64	3,49	Convergence criterion (GCONV=1E-8) satisfied.	0,2286
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	2	5,1	37	94,9	0,0481	4,21	0,89	19,82	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	3	13,0	20	87,0	0,2068	2,30	0,61	8,66	Convergence criterion (GCONV=1E-8) satisfied.	0,9431

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	7	10,3	61	89,7	0,2471	1,74	0,67	4,48	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5153	2,18	0,20	24,02	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	3	9,1	30	90,9	0,5966	1,49	0,33	6,68	Convergence criterion (GCONV=1E-8) satisfied.	0,6631
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9374	1,10	0,10	12,15	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	15	32,6	31	67,4	53	52,5	7	13,2	46	86,8	0,0168	2,85	1,16	7,00	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

01MAR2022 11:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	20	19,2	84	80,8	101	100,0	8	7,9	93	92,1	0,0183	2,59	1,14	5,88	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	15	18,3	67	81,7	71	70,3	5	7,0	66	93,0	0,0421	2,74	0,99	7,54	Convergence criterion (GCONV=1E-8) satisfied.	0,9351
	Female	22	21,2	5	22,7	17	77,3	30	29,7	3	10,0	27	90,0	0,2003	2,47	0,59	10,35	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	12	18,8	52	81,3	62	61,4	7	11,3	55	88,7	0,2217	1,78	0,70	4,51	Convergence criterion (GCONV=1E-8) satisfied.	0,1374
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	1	2,6	38	97,4	0,0190	8,07	1,01	64,52	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	7	24,1	22	75,9	23	22,8	2	8,7	21	91,3	0,1564	2,95	0,61	14,22	Convergence criterion (GCONV=1E-8) satisfied.	0,9709

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	5	7,4	63	92,6	0,0880	2,44	0,85	7,01	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5153	2,18	0,20	24,02	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	1	3,0	32	97,0	0,1418	4,47	0,50	40,04	Convergence criterion (GCONV=1E-8) satisfied.	0,6737
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9374	1,10	0,10	12,15	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	14	30,4	32	69,6	53	52,5	6	11,3	47	88,7	0,0167	3,04	1,17	7,92	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	4	3,8	100	96,2	101	100,0	3	3,0	98	97,0	0,6784	1,37	0,31	6,13	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2209	3,60	0,40	32,18	Convergence criterion (GCONV=1E-8) satisfied.	0,0619
	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2559	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9830	1,02	0,14	7,26	Convergence criterion (GCONV=1E-8) satisfied.	0,6755
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5155	2,17	0,20	23,98	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	1	4,3	22	95,7	0,3924	2,59	0,27	24,94	Convergence criterion (GCONV=1E-8) satisfied.	0,6172

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6193	0,55	0,05	6,06	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	2	6,1	31	93,9	0,6206	0,55	0,05	6,07	Convergence criterion (GCONV=1E-8) satisfied.	0,4957
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2063	3,87	0,40	37,26	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 11:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	16	15,4	88	84,6	101	100,0	4	4,0	97	96,0	0,0057	4,15	1,39	12,42	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	12	14,6	70	85,4	71	70,3	4	5,6	67	94,4	0,0712	2,72	0,88	8,43	Convergence criterion (GCONV=1E-8) satisfied.	0,0831
	Female	22	21,2	4	18,2	18	81,8	30	29,7	0	0,0	30	100,0	0,0154	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	8	12,5	56	87,5	62	61,4	3	4,8	59	95,2	0,1150	2,78	0,74	10,48	Convergence criterion (GCONV=1E-8) satisfied.	0,3649
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	1	2,6	38	97,4	0,0183	8,15	1,02	65,14	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	5	17,2	24	82,8	23	22,8	2	8,7	21	91,3	0,3566	2,12	0,41	10,95	Convergence criterion (GCONV=1E-8) satisfied.	0,5562

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	10	15,4	55	84,6	68	67,3	2	2,9	66	97,1	0,0126	5,56	1,22	25,36	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	2	6,1	31	93,9	0,3269	2,28	0,42	12,47	Convergence criterion (GCONV=1E-8) satisfied.	0,5440
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2767	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	10	21,7	36	78,3	53	52,5	2	3,8	51	96,2	0,0066	6,27	1,37	28,62	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	20	19,2	84	80,8	101	100,0	0	0	101	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	17	20,7	65	79,3	71	70,3	0	0	71	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0	30	100,0	0,0433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	12	18,8	52	81,3	62	61,4	0	0	62	100,0	0,0004	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9977
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	0	0	39	100,0	0,0040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	0	0	23	100,0	0,0088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	0	0	68	100,0	0,0006	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	7	22,6	24	77,4	33	32,7	0	0	33	100,0	0,0047	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0	15	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	11	23,9	35	76,1	53	52,5	0	0	53	100,0	0,0002	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTWDAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

01MAR2022 11:34

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

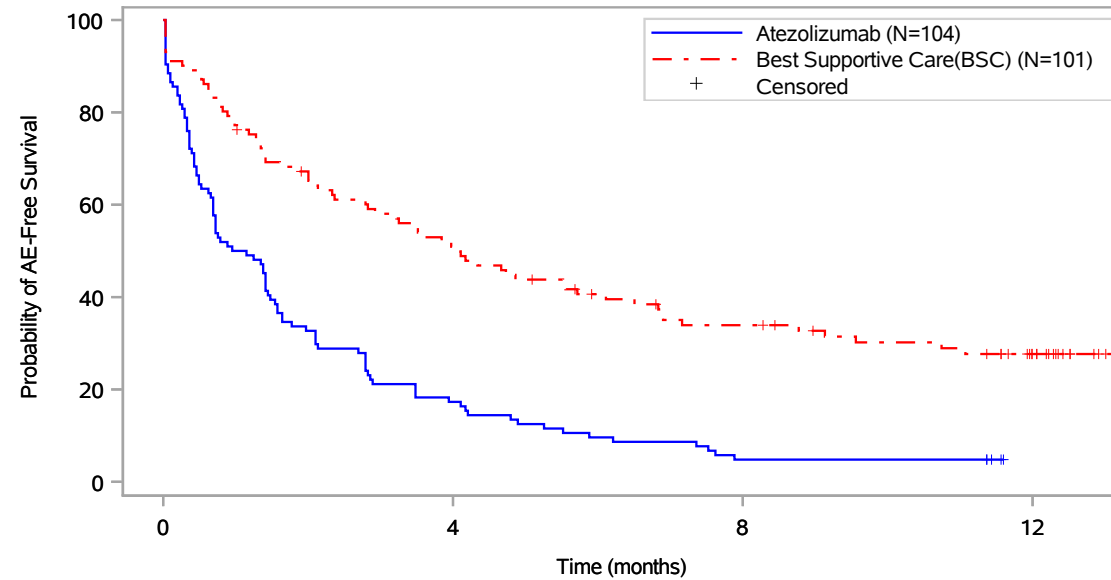
Generelle Verträglichkeit

KM Plots

Unstratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527



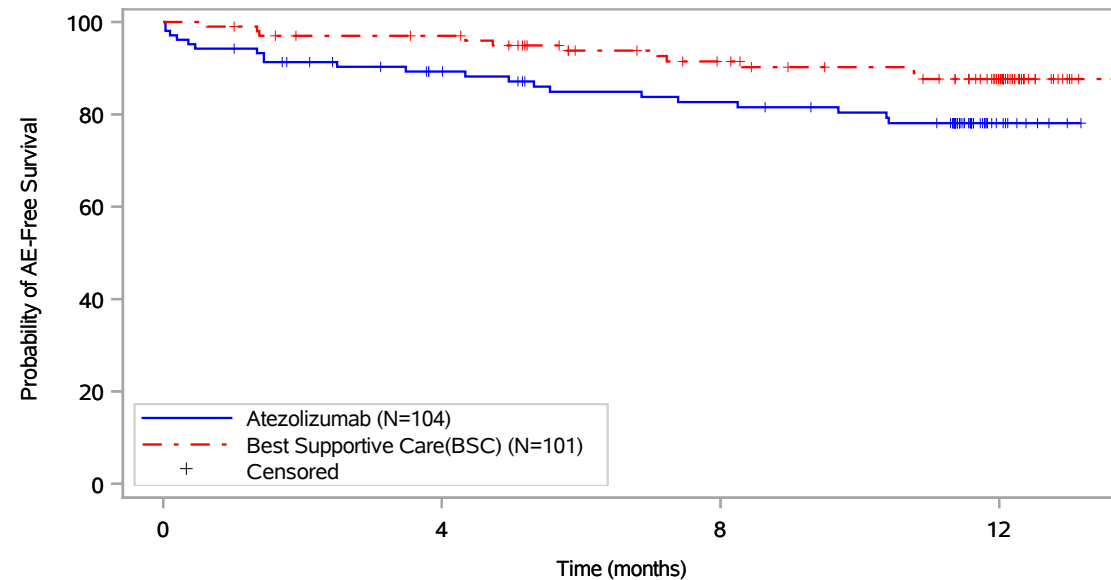
Patients at risk				
Atezolizumab (N=104)	104	18	5	NE
Best Supportive Care(BSC) (N=101)	101	50	30	14
Patients censored				
Atezolizumab (N=104)	0	0	0	NE
Best Supportive Care(BSC) (N=101)	0	2	6	17

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 18:18

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527



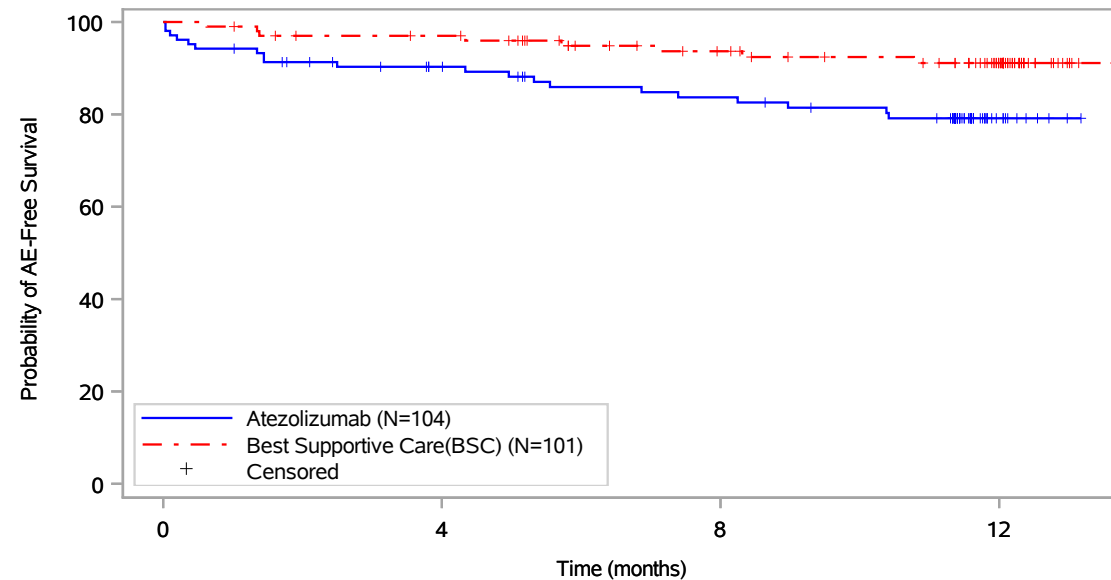
Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	84	74	9
Best Supportive Care(BSC) (N=101)	101	94	76	49
Patients censored				
Atezolizumab (N=104)	0	9	13	74
Best Supportive Care(BSC) (N=101)	0	4	17	41

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 18:22

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527



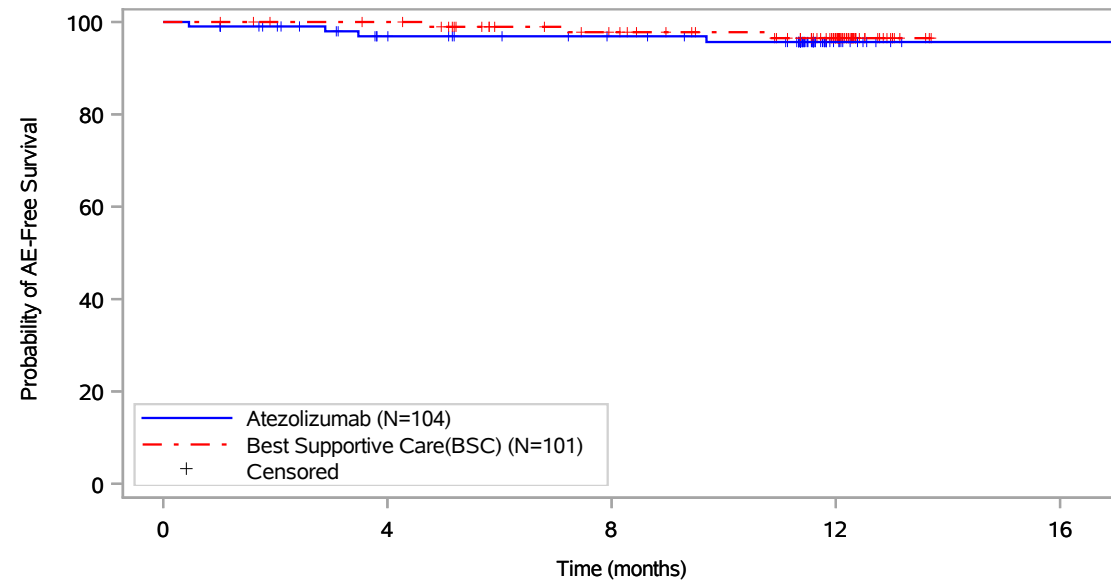
Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	85	75	10
Best Supportive Care(BSC) (N=101)	101	94	77	50
Patients censored				
Atezolizumab (N=104)	0	9	13	74
Best Supportive Care(BSC) (N=101)	0	4	18	43

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 18:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527



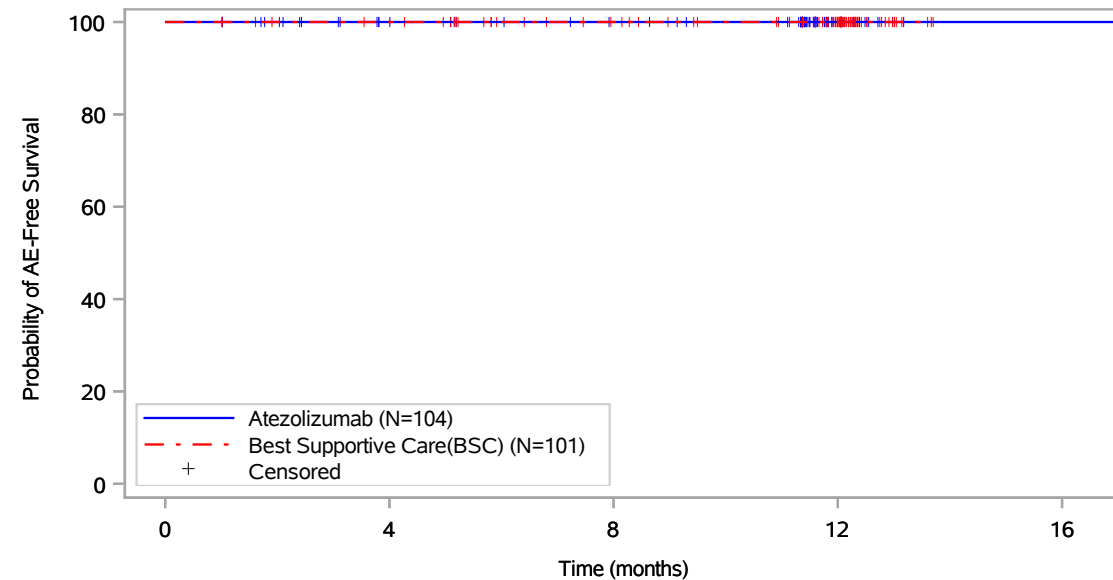
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	80	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	88	99
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 18:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 5 Adverse Event
STUDY: GO29527



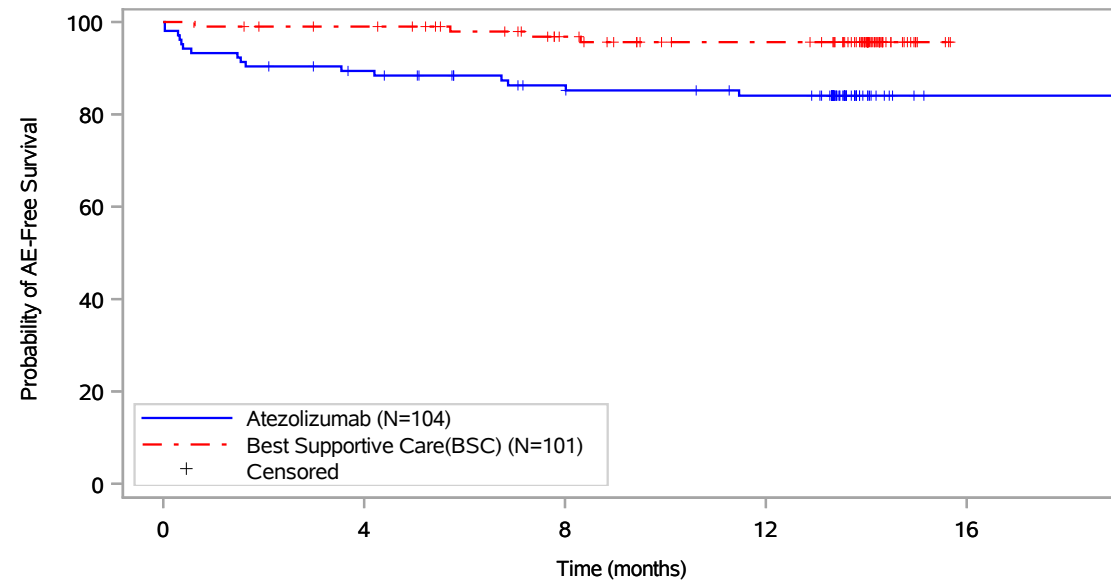
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 18:32

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527



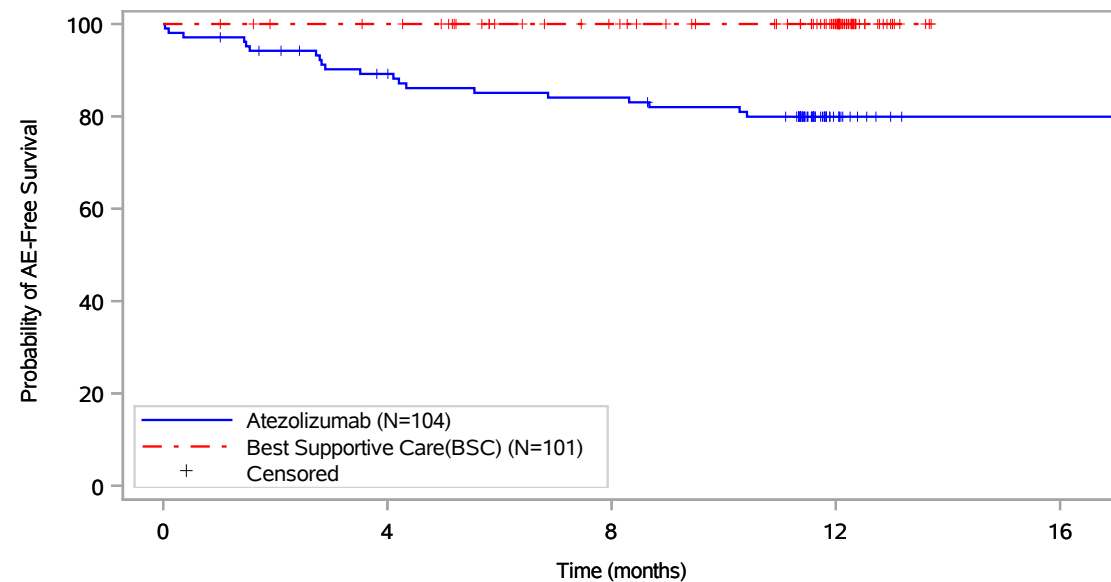
Patients at risk					
Atezolizumab (N=104)	104	90	79	74	1
Best Supportive Care(BSC) (N=101)	101	97	83	73	NE
Patients censored					
Atezolizumab (N=104)	0	3	11	14	87
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_DFS_IA/prod/output/g_km_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 18:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event leading to Atezolizumab Discontinuation
STUDY: GO29527



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	5	6	72	83
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTWDAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 18:38

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit

Outcome

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: All Patients
 MODEL: --
 STUDY: GO29527
 Outcome of Adverse Events

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care(BSC) (N=101)															
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
Any AEs																														
All	568	411	72,4	8	1,4	131	23,1	0	0,0	16	2,8	2	0,4	0	0,0	228	159	69,7	1	0,4	63	27,6	0	0,0	4	1,8	1	0,4	0	0,0
Grade 1	354	266	75,1	4	1,1	75	21,2	0	0,0	8	2,3	1	0,3	0	0,0	132	97	73,5	0	0,0	35	26,5	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	177	114	64,4	3	1,7	53	29,9	0	0,0	6	3,4	1	0,6	0	0,0	81	51	63,0	1	1,2	26	32,1	0	0,0	2	2,5	1	1,2	0	0,0
Grade 3	33	27	81,8	1	3,0	3	9,1	0	0,0	2	6,1	0	0,0	0	0,0	12	8	66,7	0	0,0	2	16,7	0	0,0	2	16,7	0	0,0	0	0,0
Grade 4	4	4	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Any SAEs																														
All	22	19	86,4	1	4,5	2	9,1	0	0,0	0	0,0	0	0,0	0	0,0	7	6	85,7	0	0,0	0	0,0	0	0,0	1	14,3	0	0,0	0	0,0
Grade 1	3	2	66,7	0	0,0	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	9	8	88,9	1	11,1	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	8	7	87,5	0	0,0	1	12,5	0	0,0	0	0,0	0	0,0	0	0,0	5	4	80,0	0	0,0	0	0,0	0	0,0	1	20,0	0	0,0	0	0,0
Grade 4	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
AEs leading to Atezolizumab discontinuation																														
All	21	13	61,9	0	0,0	7	33,3	0	0,0	1	4,8	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	2	1	50,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	2	25,0	0	0,0	6	75,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	10	9	90,0	0	0,0	0	0,0	0	0,0	1	10,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_resolved.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_resolved_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 13DEC2021 16:52

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

All

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		n/a	104	100,0	11	10,6	93	89,4	101	100,0	7	6,9	94	93,1	0,2957	1,65	0,64	4,26	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Anaemia	n/a	104	100,0	8	7,7	96	92,3	101	100,0	7	6,9	94	93,1	0,7507	1,18	0,43	3,25	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Lymphadenopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9935	1,01	0,06	16,18	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Thrombocytopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders		n/a	104	100,0	6	5,8	98	94,2	101	100,0	0	0,0	101	100,0	0,0113	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1498	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Cardiac failure	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Cardiac failure chronic	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Metabolic cardiomyopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Palpitations	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Sinus bradycardia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Congenital, familial and genetic disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3047	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Congenital, familial and genetic disorders	Gilbert's syndrome	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3047	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4040	0,49	0,09	2,69	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Ear discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Tinnitus	n/a	104	100,0	0	0,0	104	100,0	101	100,0	3	3,0	98	97,0	0,0800	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Vertigo	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Vestibular ataxia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders		n/a	104	100,0	17	16,3	87	83,7	101	100,0	2	2,0	99	98,0	0,0002	9,53	2,20	41,31	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Autoimmune thyroiditis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Hyperthyroidism	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2374	2,59	0,50	13,39	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Hypothyroidism	n/a	104	100,0	11	10,6	93	89,4	101	100,0	0	0,0	101	100,0	0,0005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		n/a	104	100,0	7	6,7	97	93,3	101	100,0	5	5,0	96	95,0	0,5136	1,46	0,46	4,61	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Blepharitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5510	0,49	0,04	5,40	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Dry eye	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Eyelid oedema	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Ocular discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Retinal detachment	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vision blurred	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1459	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Visual impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous floaters	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders		n/a	104	100,0	23	22,1	81	77,9	101	100,0	11	10,9	90	89,1	0,0211	2,28	1,11	4,68	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal distension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal hernia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain lower	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain upper	n/a	104	100,0	1	1,0	103	99,0	101	100,0	3	3,0	98	97,0	0,3154	0,33	0,03	3,19	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Bowel movement irregularity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Cheilitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Constipation	n/a	104	100,0	6	5,8	98	94,2	101	100,0	1	1,0	100	99,0	0,0453	6,57	0,79	54,88	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Diarrhoea	n/a	104	100,0	7	6,7	97	93,3	101	100,0	0	0,0	101	100,0	0,0068	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dry mouth	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0765	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dyspepsia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dysphagia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Faeces soft	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Flatulence	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Gastrooesophageal reflux disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9693	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Haemorrhoids	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3045	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Hyperaesthesia teeth	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Large intestine polyp	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Mouth ulceration	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Nausea	n/a	104	100,0	6	5,8	98	94,2	101	100,0	2	2,0	99	98,0	0,1460	3,09	0,62	15,29	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Stomatitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Toothache	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Vomiting	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5293	2,13	0,19	23,54	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		n/a	104	100,0	25	24,0	79	76,0	101	100,0	12	11,9	89	88,1	0,0163	2,27	1,14	4,53	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Asthenia	n/a	104	100,0	9	8,7	95	91,3	101	100,0	2	2,0	99	98,0	0,0310	4,63	1,00	21,44	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Catheter site haematoma	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Catheter site pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Chest discomfort	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Chest pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1578	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chills	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3045	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Fatigue	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6599	1,49	0,25	8,92	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Gait disturbance	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1587	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	3	3,0	98	97,0	0,0864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Oedema	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Oedema peripheral	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3061	3,07	0,32	29,54	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Peripheral swelling	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Pyrexia	n/a	104	100,0	11	10,6	93	89,4	101	100,0	0	0,0	101	100,0	0,0008	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	1	1,0	100	99,0	0,0875	5,32	0,62	45,50	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic steatosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9664	1,06	0,07	16,98	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)								Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test		
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
Hepatobiliary disorders	Hyperbilirubin aemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2988	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Immune system disorders		n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0426	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Immune system disorders	Hypersensitivity	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0833	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Immune system disorders	Sarcoidosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Infections and infestations		n/a	104	100,0	45	43,3	59	56,7	101	100,0	34	33,7	67	66,3	0,0446	1,58	1,01	2,46	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Infections and infestations	Bronchitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	4	4,0	97	96,0	0,1804	0,25	0,03	2,24	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Infections and infestations	Candida infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0397	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Infections and infestations	Conjunctivitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cystitis	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0595	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Empyema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3230	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Fungal pharyngitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Furuncle	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Gastroenteritis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Gastrointestinal bacterial overgrowth	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Herpes zoster	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Infectious pleural effusion	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Influenza	n/a	104	100,0	3	2,9	101	97,1	101	100,0	3	3,0	98	97,0	0,9866	1,01	0,20	5,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Laryngitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Nasopharyngitis	n/a	104	100,0	8	7,7	96	92,3	101	100,0	13	12,9	88	87,1	0,3060	0,63	0,26	1,53	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Oral fungal infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Oral herpes	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Otitis externa	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Otitis media	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Paronychia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pharyngitis	n/a	104	100,0	3	2,9	101	97,1	101	100,0	3	3,0	98	97,0	0,9982	1,00	0,20	4,96	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	1	1,0	100	99,0	0,1739	4,07	0,45	36,40	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia pneumococcal	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Prostate infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pulpitis dental	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Respiratory tract infection	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6170	1,57	0,26	9,42	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Respiratory tract infection viral	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1515	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Rhinitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1586	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Sinusitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1574	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Skin infection	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tinea infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tonsillitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tooth abscess	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3230	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tooth infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tracheitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Upper respiratory tract infection	n/a	104	100,0	3	2,9	101	97,1	101	100,0	5	5,0	96	95,0	0,5071	0,62	0,15	2,59	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Urinary tract infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,6007	0,53	0,05	5,87	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Vaginal infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Viral infection	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1566	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Viral upper respiratory tract infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications		n/a	104	100,0	6	5,8	98	94,2	101	100,0	4	4,0	97	96,0	0,4922	1,55	0,44	5,50	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Contusion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Eye contusion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fall	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5532	2,04	0,18	22,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Fracture	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Joint dislocation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Ligament sprain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9960	1,01	0,06	16,11	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Limb injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Rib fracture	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		n/a	104	100,0	34	32,7	70	67,3	101	100,0	9	8,9	92	91,1	<.0001	4,50	2,15	9,40	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	8	7,7	96	92,3	101	100,0	3	3,0	98	97,0	0,1303	2,68	0,71	10,09	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	5	4,8	99	95,2	101	100,0	3	3,0	98	97,0	0,4791	1,67	0,40	6,98	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood alkaline phosphatase increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1582	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood cholesterol increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatine increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatine phosphokinase increased	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0826	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatinine increased	n/a	104	100,0	9	8,7	95	91,3	101	100,0	1	1,0	100	99,0	0,0080	9,71	1,23	76,70	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood iron decreased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1658	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood lactate dehydrogenase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood magnesium decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3299	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood pressure increased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3326	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood thyroid stimulating hormone decreased	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0388	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood triglycerides increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood uric acid increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5755	1,96	0,18	21,62	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Creatinine renal clearance decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3113	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Gastric pH decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	International normalised ratio increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Liver function test increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5574	0,49	0,04	5,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Oxygen saturation decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Transaminases increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Urine bilirubin increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight decreased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,0635	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight increased	n/a	104	100,0	5	4,8	99	95,2	101	100,0	1	1,0	100	99,0	0,0829	5,42	0,63	46,43	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	19	18,3	85	81,7	101	100,0	12	11,9	89	88,1	0,1973	1,60	0,78	3,30	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Decreased appetite	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3313	2,92	0,30	28,03	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Dehydration	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1599	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypercholesterolaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1633	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperglycaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9999	1,00	0,14	7,10	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5704	1,98	0,18	21,80	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperuricaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5719	1,97	0,18	21,75	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypoglycaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0423	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypomagnesaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3409	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphataemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9917	0,99	0,06	15,76	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypovolaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Iron deficiency	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Vitamin D deficiency	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders		n/a	104	100,0	31	29,8	73	70,2	101	100,0	16	15,8	85	84,2	0,0066	2,27	1,24	4,16	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	104	100,0	13	12,5	91	87,5	101	100,0	5	5,0	96	95,0	0,0404	2,81	1,00	7,88	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9986	1,00	0,06	15,95	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Back pain	n/a	104	100,0	4	3,8	100	96,2	101	100,0	5	5,0	96	95,0	0,8647	0,89	0,24	3,36	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Bone pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9898	1,02	0,06	16,28	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Coccydynia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9882	1,02	0,06	16,33	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscle fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0455	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	2	2,0	99	98,0	0,4014	2,04	0,37	11,13	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Neck pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3198	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	104	100,0	4	3,8	100	96,2	101	100,0	2	2,0	99	98,0	0,3918	2,07	0,38	11,29	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Periarthritis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3409	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Spinal pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Synovial cyst	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Tendonitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	5	4,8	99	95,2	101	100,0	4	4,0	97	96,0	0,6688	1,33	0,36	4,99	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3113	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		n/a	104	100,0	26	25,0	78	75,0	101	100,0	23	22,8	78	77,2	0,6739	1,13	0,64	1,99	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Arachnoid cyst	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral arteriosclerosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral infarction	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3116	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cognitive disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Disturbance in attention	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dizziness	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2368	2,59	0,50	13,38	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Dysaesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Encephalopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Headache	n/a	104	100,0	5	4,8	99	95,2	101	100,0	5	5,0	96	95,0	0,7876	0,83	0,22	3,11	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Hypoaesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1532	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Lethargy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Loss of consciousness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Memory impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Migraine	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Myelopathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Neuropathy peripheral	n/a	104	100,0	6	5,8	98	94,2	101	100,0	1	1,0	100	99,0	0,0522	6,24	0,75	51,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Neurotoxicity	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4347	0,51	0,09	2,81	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Parosmia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3022	3,10	0,32	29,78	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Polyneuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1650	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Seizure	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Somnolence	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9862	0,98	0,06	15,60	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9847	0,97	0,06	15,56	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Tension headache	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3223	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Transient ischaemic attack	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Upper motor neurone lesion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Vocal cord paralysis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders		n/a	104	100,0	7	6,7	97	93,3	101	100,0	5	5,0	96	95,0	0,4177	1,61	0,50	5,14	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Anxiety	n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0,0	101	100,0	0,0096	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Depressed mood	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Depression	n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9522	1,06	0,15	7,54	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Insomnia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1469	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Mental status changes	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Psychiatric symptom	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3326	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Sleep disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	6	5,8	98	94,2	101	100,0	4	4,0	97	96,0	0,4953	1,55	0,44	5,49	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Acute kidney injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1460	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Dysuria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9722	1,05	0,07	16,81	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Micturition disorder	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Pollakiuria	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Proteinuria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Renal cyst	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Renal impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Urinary tract pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6601	1,49	0,25	8,92	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Balanoposthitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3113	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast discharge	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Breast pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Gynaecomastia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	31	29,8	73	70,2	101	100,0	20	19,8	81	80,2	0,0527	1,75	0,99	3,09	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Catarrh	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Cough	n/a	104	100,0	15	14,4	89	85,6	101	100,0	10	9,9	91	90,1	0,2666	1,57	0,70	3,52	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dysphonia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	8	7,7	96	92,3	101	100,0	5	5,0	96	95,0	0,2819	1,85	0,59	5,79	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Haemoptysis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1541	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Laryngospasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Lung disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6250	1,56	0,26	9,32	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pleurisy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0134	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0382	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rales	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1517	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0430	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3300	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	36	34,6	68	65,4	101	100,0	6	5,9	95	94,1	<.0001	7,32	3,08	17,38	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Actinic keratosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3299	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Alopecia	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6500	1,51	0,25	9,03	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3301	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0771	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2965	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Drug eruption	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dry skin	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0378	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Erythema	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1565	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Miliaria	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Onychoclasia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Papule	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Pruritus	n/a	104	100,0	12	11,5	92	88,5	101	100,0	2	2,0	99	98,0	0,0046	6,53	1,46	29,18	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Psoriasis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1427	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	8	7,7	96	92,3	101	100,0	0	0,0	101	100,0	0,0042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash erythematous	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash pruritic	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3116	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Scar pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Skin burning sensation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Toxic skin eruption	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Urticaria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Vitiligo	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Surgical and medical procedures		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Surgical and medical procedures	Cancer surgery	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	5	5,0	96	95,0	0,9552	1,04	0,30	3,58	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hot flush	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0394	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypotension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Orthostatic hypotension	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Phlebitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Phlebitis superficial	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Vascular stenosis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3149	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Male	82	78,8	7	8,5	75	91,5	71	70,3	5	7,0	66	93,0	0,6561	1,30	0,41	4,09	Convergence criterion (GCONV=1E-8) satisfied.	0,3700
Blood and lymphatic system disorders		Female	22	21,2	4	18,2	18	81,8	30	29,7	2	6,7	28	93,3	0,1738	3,08	0,56	16,94	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	Male	82	78,8	5	6,1	77	93,9	71	70,3	5	7,0	66	93,0	0,8796	0,91	0,26	3,14	Convergence criterion (GCONV=1E-8) satisfied.	0,3862
Blood and lymphatic system disorders	Anaemia	Female	22	21,2	3	13,6	19	86,4	30	29,7	2	6,7	28	93,3	0,3624	2,26	0,37	13,64	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Lymphadenopathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1289
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		Male	82	78,8	6	7,3	76	92,7	71	70,3	0	0,0	71	100,0	0,0179	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Cardiac disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Cardiac failure	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Cardiac failure	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Cardiac failure chronic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Metabolic cardiomyopathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Palpitations	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3552	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Sinus bradycardia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2756	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Congenital, familial and genetic disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2756	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Congenital, familial and genetic disorders	Gilbert's syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2523
Ear and labyrinth disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9894	0,99	0,16	5,92	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Ear and labyrinth disorders	Ear discomfort	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Tinnitus	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Ear and labyrinth disorders	Tinnitus	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2424	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Ear and labyrinth disorders	Vertigo	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Ear and labyrinth disorders	Vestibular ataxia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Male	82	78,8	15	18,3	67	81,7	71	70,3	1	1,4	70	98,6	0,0005	14,76	1,95	111,87	Convergence criterion (GCONV=1E-8) satisfied.	0,3458
Endocrine disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2873	3,41	0,31	37,61	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Autoimmune thyroiditis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2225	3,59	0,40	32,17	Convergence criterion (GCONV=1E-8) satisfied.	0,6272
Endocrine disorders	Hyperthyroidism	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7143	1,67	0,10	26,72	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	Male	82	78,8	10	12,2	72	87,8	71	70,3	0	0,0	71	100,0	0,0020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Endocrine disorders	Hypothyroidism	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	4	5,6	67	94,4	0,8645	1,12	0,30	4,18	Convergence criterion (GCONV=1E-8) satisfied.	0,4438
Eye disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2789	3,47	0,31	38,36	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Blepharitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Eye disorders	Blepharitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4843	0,44	0,04	4,80	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Dry eye	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Eye disorders	Eyelid oedema	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Ocular discomfort	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Retinal detachment	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1769	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Eye disorders	Vision blurred	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Visual impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous floaters	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	17	20,7	65	79,3	71	70,3	7	9,9	64	90,1	0,0489	2,36	0,98	5,70	Convergence criterion (GCONV=1E-8) satisfied.	0,9491
Gastrointestinal disorders		Female	22	21,2	6	27,3	16	72,7	30	29,7	4	13,3	26	86,7	0,1931	2,28	0,64	8,13	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Abdominal distension	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders	Abdominal hernia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Abdominal pain lower	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1341	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1311
Gastrointestinal disorders	Abdominal pain upper	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Gastrointestinal disorders	Bowel movement irregularity	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Cheilitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0441	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2382
Gastrointestinal disorders	Constipation	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,3676	2,87	0,26	31,67	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0,0	71	100,0	0,0331	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Gastrointestinal disorders	Diarrhoea	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0753	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1749	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Gastrointestinal disorders	Dry mouth	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3438	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dyspepsia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders	Dysphagia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Faeces soft	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Gastrointestinal disorders	Flatulence	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0639
Gastrointestinal disorders	Gastrooesophageal reflux disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Haemorrhoids	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Haemorrhoids	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Hyperaesthesia teeth	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Large intestine polyp	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Mouth ulceration	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3661	2,72	0,28	26,18	Convergence criterion (GCONV=1E-8) satisfied.	0,7368

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Nausea	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1477	4,58	0,48	44,12	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3539	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Stomatitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Toothache	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0295
Gastrointestinal disorders	Vomiting	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Male	82	78,8	20	24,4	62	75,6	71	70,3	6	8,5	65	91,5	0,0077	3,24	1,30	8,08	Convergence criterion (GCONV=1E-8) satisfied.	0,1874

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions		Female	22	21,2	5	22,7	17	77,3	30	29,7	6	20,0	24	80,0	0,7680	1,20	0,36	3,92	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	Male	82	78,8	9	11,0	73	89,0	71	70,3	1	1,4	70	98,6	0,0175	8,16	1,03	64,47	Convergence criterion (GCONV=1E-8) satisfied.	0,0752
General disorders and administration site conditions	Asthenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Catheter site haematoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Catheter site pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administration site conditions	Chest discomfort	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1304	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
General disorders and administration site conditions	Chest pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3381	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chills	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6306	1,79	0,16	19,71	Convergence criterion (GCONV=1E-8) satisfied.	0,8971
General disorders and administration site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8161	1,39	0,09	22,18	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Gait disturbance	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2518	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4956
General disorders and administration site conditions	Oedema peripheral	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,3727	2,84	0,26	31,37	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
General disorders and administration site conditions	Peripheral swelling	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Male	82	78,8	10	12,2	72	87,8	71	70,3	0	0,0	71	100,0	0,0024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administration site conditions	Pyrexia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	1	1,4	70	98,6	0,1289	4,55	0,53	38,92	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9526	0,92	0,06	14,71	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Hepatobiliary disorders	Hepatic steatosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3387	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hyperbilirubinemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1009	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Immune system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Immune system disorders	Hypersensitivity	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Sarcoidosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Male	82	78,8	36	43,9	46	56,1	71	70,3	17	23,9	54	76,1	0,0026	2,37	1,33	4,24	Convergence criterion (GCONV=1E-8) satisfied.	0,0238
Infections and infestations		Female	22	21,2	9	40,9	13	59,1	30	29,7	17	56,7	13	43,3	0,5068	0,76	0,34	1,71	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Bronchitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	4	5,6	67	94,4	0,1342	0,22	0,02	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,9972
Infections and infestations	Bronchitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Candida infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0631	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9960
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Conjunctivitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1887	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cystitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Infections and infestations	Empyema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Fungal pharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Furuncle	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastroenteritis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Gastroenteritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4386	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Infections and infestations	Gastrointestinal bacterial overgrowth	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Infections and infestations	Herpes zoster	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1771	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Infectious pleural effusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9098	0,89	0,13	6,34	Convergence criterion (GCONV=1E-8) satisfied.	0,7696

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Influenza	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Laryngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4386	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	Male	82	78,8	8	9,8	74	90,2	71	70,3	8	11,3	63	88,7	0,8630	0,92	0,34	2,44	Convergence criterion (GCONV=1E-8) satisfied.	0,0413
Infections and infestations	Nasopharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	5	16,7	25	83,3	0,0676	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral fungal infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3469	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Oral fungal infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Infections and infestations	Oral herpes	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Otitis externa	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3485	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Otitis media	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Paronychia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3774	2,66	0,28	25,61	Convergence criterion (GCONV=1E-8) satisfied.	0,0850
Infections and infestations	Pharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2459	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2239	3,57	0,40	31,93	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Pneumonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia pneumococcal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Prostate infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pulpitis dental	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Pulpitis dental	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3575	2,77	0,29	26,61	Convergence criterion (GCONV=1E-8) satisfied.	0,2015
Infections and infestations	Respiratory tract infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1816	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Respiratory tract infection viral	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Infections and infestations	Rhinitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1820	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Sinusitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Skin infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Tinea infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2162	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Infections and infestations	Tonsillitis	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth abscess	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2906	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Tooth abscess	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Tooth infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Tracheitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3638	2,73	0,28	26,29	Convergence criterion (GCONV=1E-8) satisfied.	0,0299
Infections and infestations	Upper respiratory tract infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	4	13,3	26	86,7	0,1048	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Urinary tract infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,8988	0,86	0,08	9,44	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Vaginal infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1828	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Viral infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Viral upper respiratory tract infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2166	3,63	0,41	32,51	Convergence criterion (GCONV=1E-8) satisfied.	0,3606

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications		Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9635	1,04	0,17	6,26	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Contusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Eye contusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1828	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0747

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fall	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Injury, poisoning and procedural complications	Fracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Joint dislocation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0687

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Ligament sprain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Injury, poisoning and procedural complications	Limb injury	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Injury, poisoning and procedural complications	Rib fracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	30	36,6	52	63,4	71	70,3	5	7,0	66	93,0	<.0001	6,47	2,50	16,70	Convergence criterion (GCONV=1E-8) satisfied.	0,1029
Investigations		Female	22	21,2	4	18,2	18	81,8	30	29,7	4	13,3	26	86,7	0,5467	1,53	0,38	6,12	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Male	82	78,8	6	7,3	76	92,7	71	70,3	2	2,8	69	97,2	0,2036	2,71	0,55	13,42	Convergence criterion (GCONV=1E-8) satisfied.	0,9888
Investigations	Alanine aminotransferase increased	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,4086	2,65	0,24	29,23	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	4	4,9	78	95,1	71	70,3	2	2,8	69	97,2	0,5010	1,78	0,33	9,70	Convergence criterion (GCONV=1E-8) satisfied.	0,8882
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8404	1,33	0,08	21,28	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1846	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Investigations	Blood alkaline phosphatase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood cholesterol increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood creatine increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1016	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood creatine phosphokinase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	Male	82	78,8	6	7,3	76	92,7	71	70,3	1	1,4	70	98,6	0,0733	5,56	0,67	46,19	Convergence criterion (GCONV=1E-8) satisfied.	0,2726
Investigations	Blood creatinine increased	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0258	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1914	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Investigations	Blood iron decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood lactate dehydrogenase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood magnesium decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood magnesium decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3001	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Investigations	Blood pressure increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0538	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Investigations	Blood thyroid stimulating hormone decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood triglycerides increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6495	1,73	0,16	19,11	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood uric acid increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Creatinine renal clearance decreased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2776	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Investigations	Gamma-glutamyltransferase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Gastric pH decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	International normalised ratio increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Liver function test increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Liver function test increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0716
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2322	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Oxygen saturation decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Transaminases increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Urine bilirubin increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	Weight decreased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0953	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3024
Investigations	Weight increased	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2656	3,58	0,32	39,50	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	13	15,9	69	84,1	71	70,3	10	14,1	61	85,9	0,7693	1,13	0,50	2,58	Convergence criterion (GCONV=1E-8) satisfied.	0,0974
Metabolism and nutrition disorders		Female	22	21,2	6	27,3	16	72,7	30	29,7	2	6,7	28	93,3	0,0343	4,78	0,96	23,72	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6538	1,72	0,16	18,97	Convergence criterion (GCONV=1E-8) satisfied.	0,3281
Metabolism and nutrition disorders	Decreased appetite	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Dehydration	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Metabolism and nutrition disorders	Dehydration	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1327	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9956
Metabolism and nutrition disorders	Hypercholesterolaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4858	0,44	0,04	4,81	Convergence criterion (GCONV=1E-8) satisfied.	0,1298
Metabolism and nutrition disorders	Hyperglycaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6420	1,75	0,16	19,34	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6439	1,75	0,16	19,28	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Metabolism and nutrition disorders	Hyperuricaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypoglycaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0997	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypomagnesaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Metabolism and nutrition disorders	Hypomagnesaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0694
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Metabolism and nutrition disorders	Hypovolaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Metabolism and nutrition disorders	Iron deficiency	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Vitamin D deficiency	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Male	82	78,8	24	29,3	58	70,7	71	70,3	9	12,7	62	87,3	0,0069	2,77	1,28	5,99	Convergence criterion (GCONV=1E-8) satisfied.	0,5202
Musculoskeletal and connective tissue disorders		Female	22	21,2	7	31,8	15	68,2	30	29,7	7	23,3	23	76,7	0,3374	1,67	0,58	4,78	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	Male	82	78,8	8	9,8	74	90,2	71	70,3	2	2,8	69	97,2	0,0763	3,70	0,78	17,43	Convergence criterion (GCONV=1E-8) satisfied.	0,8347
Musculoskeletal and connective tissue disorders	Arthralgia	Female	22	21,2	5	22,7	17	77,3	30	29,7	3	10,0	27	90,0	0,1372	2,83	0,67	11,89	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1295
Musculoskeletal and connective tissue disorders	Arthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4237	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Back pain	Male	82	78,8	3	3,7	79	96,3	71	70,3	3	4,2	68	95,8	0,9591	1,04	0,21	5,31	Convergence criterion (GCONV=1E-8) satisfied.	0,8897
Musculoskeletal and connective tissue disorders	Back pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,7923	0,73	0,07	8,00	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Musculoskeletal and connective tissue disorders	Bone pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7671	1,52	0,09	24,24	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Coccydynia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9317	0,89	0,06	14,16	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Muscle fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3485	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Muscle spasms	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1830	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0907	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0967	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2260	3,55	0,40	31,77	Convergence criterion (GCONV=1E-8) satisfied.	0,1574
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Neck pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Osteoarthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3578	2,77	0,29	26,60	Convergence criterion (GCONV=1E-8) satisfied.	0,7546
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8352	1,34	0,08	21,44	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Periarthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Musculoskeletal and connective tissue disorders	Spinal pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders	Synovial cyst	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Tendonitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	4	4,9	78	95,1	71	70,3	3	4,2	68	95,8	0,7698	1,25	0,28	5,62	Convergence criterion (GCONV=1E-8) satisfied.	0,8675

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7106	1,68	0,11	26,89	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2813	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	16	19,5	66	80,5	71	70,3	15	21,1	56	78,9	0,9162	0,96	0,48	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,2819
Nervous system disorders		Female	22	21,2	10	45,5	12	54,5	30	29,7	8	26,7	22	73,3	0,2322	1,78	0,68	4,62	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Arachnoid cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Arachnoid cyst	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Cerebral arteriosclerosis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Cognitive disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Disturbance in attention	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	Male	82	78,8	3	3,7	79	96,3	71	70,3	2	2,8	69	97,2	0,7357	1,36	0,23	8,14	Convergence criterion (GCONV=1E-8) satisfied.	0,1232
Nervous system disorders	Dizziness	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0838	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dysaesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Dysaesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Encephalopathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9386	0,93	0,13	6,57	Convergence criterion (GCONV=1E-8) satisfied.	0,9019
Nervous system disorders	Headache	Female	22	21,2	3	13,6	19	86,4	30	29,7	3	10,0	27	90,0	0,9611	1,05	0,17	6,28	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1290	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
Nervous system disorders	Hypoaesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Lethargy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Loss of consciousness	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Memory impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Migraine	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Myelopathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Neuropathy peripheral	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2124	3,68	0,41	32,98	Convergence criterion (GCONV=1E-8) satisfied.	0,2922
Nervous system disorders	Neuropathy peripheral	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Neurotoxicity	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9256	0,91	0,13	6,47	Convergence criterion (GCONV=1E-8) satisfied.	0,2209
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Nervous system disorders	Parosmia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2367	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6189	1,82	0,17	20,10	Convergence criterion (GCONV=1E-8) satisfied.	0,3225

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1360	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
Nervous system disorders	Polyneuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Seizure	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9223	0,87	0,05	13,92	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Somnolence	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9123	0,86	0,05	13,69	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Tension headache	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Transient ischaemic attack	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Upper motor neurone lesion	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Vocal cord paralysis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		Male	82	78,8	4	4,9	78	95,1	71	70,3	2	2,8	69	97,2	0,3666	2,17	0,39	12,19	Convergence criterion (GCONV=1E-8) satisfied.	0,9711
Psychiatric disorders		Female	22	21,2	3	13,6	19	86,4	30	29,7	3	10,0	27	90,0	0,5291	1,66	0,33	8,27	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0479	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Psychiatric disorders	Anxiety	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0669	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Psychiatric disorders	Depressed mood	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1205
Psychiatric disorders	Depression	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2839	3,43	0,31	37,90	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Psychiatric disorders	Insomnia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Psychiatric disorders	Insomnia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Psychiatric disorders	Mental status changes	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3001	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Psychiatric disorders	Psychiatric symptom	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Psychiatric disorders	Sleep disorder	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	3	4,2	68	95,8	0,5637	1,52	0,36	6,37	Convergence criterion (GCONV=1E-8) satisfied.	0,9959

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7751	1,49	0,09	23,90	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Acute kidney injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9493	0,91	0,06	14,62	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Dysuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Renal and urinary disorders	Lower urinary tract symptoms	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Micturition disorder	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Renal and urinary disorders	Micturition disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4237	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Renal and urinary disorders	Pollakiuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Proteinuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Renal and urinary disorders	Renal cyst	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Renal impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Urinary tract pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6419	1,75	0,16	19,35	Convergence criterion (GCONV=1E-8) satisfied.	0,9197
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2776	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Reproductive system and breast disorders	Balanoposthitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Reproductive system and breast disorders	Breast discharge	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3570	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Breast pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Gynaecomastia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	27	32,9	55	67,1	71	70,3	13	18,3	58	81,7	0,0208	2,17	1,11	4,24	Convergence criterion (GCONV=1E-8) satisfied.	0,1962
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	4	18,2	18	81,8	30	29,7	7	23,3	23	76,7	0,6921	0,78	0,23	2,68	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Catarrh	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	Male	82	78,8	13	15,9	69	84,1	71	70,3	7	9,9	64	90,1	0,2288	1,75	0,69	4,41	Convergence criterion (GCONV=1E-8) satisfied.	0,5848
Respiratory, thoracic and mediastinal disorders	Cough	Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9501	0,94	0,16	5,66	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Dysphonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	7	8,5	75	91,5	71	70,3	3	4,2	68	95,8	0,1858	2,47	0,62	9,86	Convergence criterion (GCONV=1E-8) satisfied.	0,4690
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,8005	0,73	0,07	8,11	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3552	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1821	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Lung disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9179	0,90	0,13	6,40	Convergence criterion (GCONV=1E-8) satisfied.	0,1938

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Respiratory, thoracic and mediastinal disorders	Pleurisy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1030	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,0027	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Productive cough	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Rales	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Rales	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1805	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	25	30,5	57	69,5	71	70,3	3	4,2	68	95,8	<.0001	8,66	2,61	28,69	Convergence criterion (GCONV=1E-8) satisfied.	0,8406
Skin and subcutaneous tissue disorders		Female	22	21,2	11	50,0	11	50,0	30	29,7	3	10,0	27	90,0	0,0004	7,19	2,00	25,87	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Actinic keratosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0850
Skin and subcutaneous tissue disorders	Alopecia	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1394	4,71	0,49	45,35	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Skin and subcutaneous tissue disorders	Dermatitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1011	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3347	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Drug eruption	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1751	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Skin and subcutaneous tissue disorders	Dry skin	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0670	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Erythema	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Skin and subcutaneous tissue disorders	Miliaria	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Onychoclasia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Papule	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Pruritus	Male	82	78,8	9	11,0	73	89,0	71	70,3	1	1,4	70	98,6	0,0144	8,53	1,08	67,38	Convergence criterion (GCONV=1E-8) satisfied.	0,7261
Skin and subcutaneous tissue disorders	Pruritus	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1233	4,97	0,52	47,75	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1747	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Skin and subcutaneous tissue disorders	Psoriasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0,0	71	100,0	0,0325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash erythematous	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash maculo-papular	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash pruritic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Scar pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Skin burning sensation	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Toxic skin eruption	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Toxic skin eruption	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Urticaria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Vitiligo	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Surgical and medical procedures		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Surgical and medical proceders	Cancer surgery	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	3	4,2	68	95,8	0,8922	0,90	0,18	4,44	Convergence criterion (GCONV=1E-8) satisfied.	0,6801
Vascular disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	2	6,7	28	93,3	0,6293	1,61	0,23	11,48	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Hot flush	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1737	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Hypertension	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0763	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Vascular disorders	Hypotension	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Orthostatic hypotension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Orthostatic hypotension	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Phlebitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Phlebitis superficial	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2846	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Vascular stenosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	8	12,5	56	87,5	62	61,4	5	8,1	57	91,9	0,3606	1,68	0,55	5,13	Convergence criterion (GCONV=1E-8) satisfied.	0,9485
Blood and lymphatic system disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6185	1,57	0,26	9,40	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	5	8,1	57	91,9	0,9684	1,03	0,30	3,54	Convergence criterion (GCONV=1E-8) satisfied.	0,7006
Blood and lymphatic system disorders	Anaemia	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6185	1,57	0,26	9,40	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Lymphadenopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9994	1,00	0,06	16,01	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0738	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Cardiac disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Cardiac disorders	Atrial fibrillation	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Cardiac failure	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Cardiac failure	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Cardiac failure chronic	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Metabolic cardiomyopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Palpitations	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2969	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3121	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Sinus bradycardia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5267	2,13	0,19	23,51	Convergence criterion (GCONV=1E-8) satisfied.	0,0443
		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	3	7,7	36	92,3	0,0780	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Tinnitus	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3270	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Ear and labyrinth disorders	Tinnitus	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1520	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Ear and labyrinth disorders	Vertigo	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Ear and labyrinth disorders	Vestibular ataxia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	12	18,8	52	81,3	62	61,4	1	1,6	61	98,4	0,0012	13,42	1,74	103,40	Convergence criterion (GCONV=1E-8) satisfied.	0,5545
Endocrine disorders		>= 65	40	38,5	5	12,5	35	87,5	39	38,6	1	2,6	38	97,4	0,0763	5,59	0,65	47,90	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Autoimmune thyroiditis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0927	5,21	0,61	44,68	Convergence criterion (GCONV=1E-8) satisfied.	0,0823
Endocrine disorders	Hyperthyroidism	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	< 65	64	61,5	7	10,9	57	89,1	62	61,4	0	0,0	62	100,0	0,0059	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Endocrine disorders	Hypothyroidism	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0342	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5351	2,10	0,19	23,18	Convergence criterion (GCONV=1E-8) satisfied.	0,7062

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		>= 65	40	38,5	5	12,5	35	87,5	39	38,6	4	10,3	35	89,7	0,7375	1,25	0,34	4,67	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Blepharitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3137
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9855	0,97	0,06	15,58	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Dry eye	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Eyelid oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Ocular discomfort	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Ocular discomfort	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Retinal detachment	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Eye disorders	Vision blurred	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Visual impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous floaters	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	14	21,9	50	78,1	62	61,4	9	14,5	53	85,5	0,2208	1,68	0,73	3,89	Convergence criterion (GCONV=1E-8) satisfied.	0,2077
Gastrointestinal disorders		>= 65	40	38,5	9	22,5	31	77,5	39	38,6	2	5,1	37	94,9	0,0213	5,10	1,09	23,83	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal distension	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal hernia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1441	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Abdominal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal pain lower	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9895	1,02	0,06	16,30	Convergence criterion (GCONV=1E-8) satisfied.	0,1858
Gastrointestinal disorders	Abdominal pain upper	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1520	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Bowel movement irregularity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Cheilitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,3118	3,04	0,32	29,34	Convergence criterion (GCONV=1E-8) satisfied.	0,2670
Gastrointestinal disorders	Constipation	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0435	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Gastrointestinal disorders	Diarrhoea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0751	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Gastrointestinal disorders	Dry mouth	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dyspepsia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3133	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Dyspepsia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Dysphagia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Faeces soft	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Flatulence	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9698	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Gastroesophageal reflux disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3090	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Haemorrhoids	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Hyperaesthesia teeth	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Large intestine polyp	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Mouth ulceration	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Nausea	< 65	64	61,5	3	4,7	61	95,3	62	61,4	2	3,2	60	96,8	0,6295	1,55	0,26	9,27	Convergence criterion (GCONV=1E-8) satisfied.	0,1290
Gastrointestinal disorders	Nausea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0772	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Stomatitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Toothache	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5208	2,16	0,19	23,97	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Gastrointestinal disorders	Vomiting	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		< 65	64	61,5	15	23,4	49	76,6	62	61,4	6	9,7	56	90,3	0,0281	2,77	1,07	7,13	Convergence criterion (GCONV=1E-8) satisfied.	0,5565
General disorders and administration site conditions		>= 65	40	38,5	10	25,0	30	75,0	39	38,6	6	15,4	33	84,6	0,2508	1,80	0,65	4,97	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0908	5,25	0,61	44,92	Convergence criterion (GCONV=1E-8) satisfied.	0,8511
General disorders and administration site conditions	Asthenia	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	1	2,6	38	97,4	0,1894	3,90	0,44	34,90	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Catheter site haematoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Catheter site pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Catheter site pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Chest discomfort	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2943	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions	Chest pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Chills	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Chills	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5511	2,04	0,19	22,55	Convergence criterion (GCONV=1E-8) satisfied.	0,6866
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9836	0,97	0,06	15,53	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions	Gait disturbance	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1650	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Oedema	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,3061	3,07	0,32	29,53	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions	Oedema peripheral	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Peripheral swelling	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0245	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	0	0,0	39	100,0	0,0124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1544	4,30	0,48	38,51	Convergence criterion (GCONV=1E-8) satisfied.	0,5326
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9698	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic steatosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Hyperbilirubin aemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0409	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0799	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9963
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Sarcoidosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		< 65	64	61,5	26	40,6	38	59,4	62	61,4	22	35,5	40	64,5	0,2859	1,36	0,77	2,40	Convergence criterion (GCONV=1E-8) satisfied.	0,4781
Infections and infestations		>= 65	40	38,5	19	47,5	21	52,5	39	38,6	12	30,8	27	69,2	0,0666	1,95	0,94	4,04	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1742	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2818
Infections and infestations	Bronchitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	2	5,1	37	94,9	0,5299	0,47	0,04	5,20	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Candida infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Conjunctivitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9962
Infections and infestations	Cystitis	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0880	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3399	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Empyema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Fungal pharyngitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Furuncle	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Furuncle	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Gastroenteritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Gastrointestinal bacterial overgrowth	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3017	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Herpes zoster	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Infectious pleural effusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	< 65	64	61,5	1	1,6	63	98,4	62	61,4	3	4,8	59	95,2	0,3307	0,34	0,04	3,29	Convergence criterion (GCONV=1E-8) satisfied.	0,0498
Infections and infestations	Influenza	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1599	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Laryngitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Nasopharyngitis	< 65	64	61,5	6	9,4	58	90,6	62	61,4	8	12,9	54	87,1	0,6936	0,81	0,28	2,33	Convergence criterion (GCONV=1E-8) satisfied.	0,4502
Infections and infestations	Nasopharyngitis	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	5	12,8	34	87,2	0,2273	0,38	0,07	1,95	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Oral fungal infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Oral herpes	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Otitis externa	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Otitis media	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Paronychia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,2972	3,13	0,33	30,13	Convergence criterion (GCONV=1E-8) satisfied.	0,0458
Infections and infestations	Pharyngitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1547	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1624	4,20	0,47	37,64	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Infections and infestations	Pneumonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia pneumococcal	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Prostate infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Prostate infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pulpitis dental	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5858	0,52	0,05	5,73	Convergence criterion (GCONV=1E-8) satisfied.	0,0925
Infections and infestations	Respiratory tract infection	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1425	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Infections and infestations	Respiratory tract infection viral	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Rhinitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Sepsis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Sinusitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Skin infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Tinea infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tonsillitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Tonsillitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3399	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tooth abscess	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tooth infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tracheitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9637	1,05	0,15	7,43	Convergence criterion (GCONV=1E-8) satisfied.	0,4375

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Upper respiratory tract infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	3	7,7	36	92,3	0,3053	0,32	0,03	3,13	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0483
Infections and infestations	Urinary tract infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1591	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Vaginal infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Viral infection	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1667	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Viral upper respiratory tract infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications		< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,2860	3,21	0,33	30,84	Convergence criterion (GCONV=1E-8) satisfied.	0,3807
Injury, poisoning and procedural complications		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	3	7,7	36	92,3	0,9639	0,96	0,19	4,78	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Contusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Eye contusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fall	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Injury, poisoning and procedural complications	Fall	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5813	1,94	0,18	21,40	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Fracture	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3245	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Joint dislocation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Ligament sprain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0927
Injury, poisoning and procedural complications	Ligament sprain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Limb injury	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Rib fracture	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		< 65	64	61,5	23	35,9	41	64,1	62	61,4	7	11,3	55	88,7	0,0005	4,04	1,73	9,44	Convergence criterion (GCONV=1E-8) satisfied.	0,6123
Investigations		>= 65	40	38,5	11	27,5	29	72,5	39	38,6	2	5,1	37	94,9	0,0082	5,98	1,32	26,99	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	< 65	64	61,5	5	7,8	59	92,2	62	61,4	3	4,8	59	95,2	0,4667	1,69	0,40	7,08	Convergence criterion (GCONV=1E-8) satisfied.	0,1321
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0836	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	3	4,8	59	95,2	0,9884	1,01	0,20	5,02	Convergence criterion (GCONV=1E-8) satisfied.	0,1351
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Blood alkaline phosphatase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood cholesterol increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood creatine increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1529	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Investigations	Blood creatine phosphokinase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	< 65	64	61,5	6	9,4	58	90,6	62	61,4	0	0,0	62	100,0	0,0102	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1563
Investigations	Blood creatinine increased	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,3180	3,00	0,31	28,81	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1606	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Investigations	Blood iron decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood lactate dehydrogenase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood lactate dehydrogenase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood magnesium decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3297	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood pressure increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0790	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Blood thyroid stimulating hormone decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood triglycerides increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2925
Investigations	Blood uric acid increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9504	0,92	0,06	14,68	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Creatinine renal clearance decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gamma-glutamyltransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gastric pH decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	International normalised ratio increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	International normalised ratio increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Liver function test increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5690	0,50	0,05	5,57	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Oxygen saturation decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3023	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Transaminases increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Urine bilirubin increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,0833	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	Weight decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0743	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2086
Investigations	Weight increased	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5263	2,13	0,19	23,57	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	15	23,4	49	76,6	62	61,4	6	9,7	56	90,3	0,0304	2,73	1,06	7,05	Convergence criterion (GCONV=1E-8) satisfied.	0,0622
Metabolism and nutrition disorders		>= 65	40	38,5	4	10,0	36	90,0	39	38,6	6	15,4	33	84,6	0,4871	0,64	0,18	2,28	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Decreased appetite	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1511	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1796
Metabolism and nutrition disorders	Decreased appetite	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9929	0,99	0,06	15,79	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1488	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Metabolism and nutrition disorders	Dehydration	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Metabolism and nutrition disorders	Hypercholesterolaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1542	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5341	2,10	0,19	23,22	Convergence criterion (GCONV=1E-8) satisfied.	0,1787
Metabolism and nutrition disorders	Hyperglycaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1589	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0485
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3021
Metabolism and nutrition disorders	Hyperuricaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9929	0,99	0,06	15,79	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypoglycaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1514	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypomagnesaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9925	1,01	0,06	16,21	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypovolaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Iron deficiency	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Vitamin D deficiency	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	18	28,1	46	71,9	62	61,4	9	14,5	53	85,5	0,0465	2,21	0,99	4,92	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	13	32,5	27	67,5	39	38,6	7	17,9	32	82,1	0,0564	2,41	0,95	6,14	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	< 65	64	61,5	7	10,9	57	89,1	62	61,4	3	4,8	59	95,2	0,1663	2,52	0,65	9,73	Convergence criterion (GCONV=1E-8) satisfied.	0,8171
Musculoskeletal and connective tissue disorders	Arthralgia	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	2	5,1	37	94,9	0,1230	3,28	0,66	16,28	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3314	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	< 65	64	61,5	4	6,3	60	93,8	62	61,4	3	4,8	59	95,2	0,6914	1,35	0,30	6,04	Convergence criterion (GCONV=1E-8) satisfied.	0,0907
Musculoskeletal and connective tissue disorders	Back pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,2227	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1024
Musculoskeletal and connective tissue disorders	Bone pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Coccydynia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9868	0,98	0,06	15,68	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Limb discomfort	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscle fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1623	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1753	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1476	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9981	1,00	0,06	16,05	Convergence criterion (GCONV=1E-8) satisfied.	0,5376
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,2960	3,14	0,33	30,21	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Neck pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2987	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1584	4,26	0,48	38,10	Convergence criterion (GCONV=1E-8) satisfied.	0,1017
Musculoskeletal and connective tissue disorders	Pain in extremity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Periarthritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Spinal pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Spinal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Synovial cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Tendonitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9722	1,04	0,15	7,35	Convergence criterion (GCONV=1E-8) satisfied.	0,7918

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,5830	1,65	0,27	10,04	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	13	20,3	51	79,7	62	61,4	14	22,6	48	77,4	0,7657	0,89	0,41	1,92	Convergence criterion (GCONV=1E-8) satisfied.	0,3763
Nervous system disorders		>= 65	40	38,5	13	32,5	27	67,5	39	38,6	9	23,1	30	76,9	0,3537	1,49	0,64	3,49	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Arachnoid cyst	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Arachnoid cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebral arteriosclerosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral infarction	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cognitive disorder	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Disturbance in attention	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9843	1,02	0,14	7,24	Convergence criterion (GCONV=1E-8) satisfied.	0,0897
Nervous system disorders	Dizziness	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dysaesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Dysaesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Encephalopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	< 65	64	61,5	4	6,3	60	93,8	62	61,4	3	4,8	59	95,2	0,9549	1,05	0,21	5,19	Convergence criterion (GCONV=1E-8) satisfied.	0,6199
Nervous system disorders	Headache	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	2	5,1	37	94,9	0,5916	0,52	0,05	5,78	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Hypoaesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Lethargy	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Loss of consciousness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Memory impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Migraine	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3314	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Myelopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Neuropathy peripheral	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0240	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0828
Nervous system disorders	Neuropathy peripheral	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9677	1,06	0,07	16,95	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Neurotoxicity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	3	4,8	59	95,2	0,6808	0,69	0,11	4,13	Convergence criterion (GCONV=1E-8) satisfied.	0,3430
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Parosmia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9855	1,03	0,06	16,40	Convergence criterion (GCONV=1E-8) satisfied.	0,1840

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1590	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Nervous system disorders	Polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Seizure	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9865	0,98	0,06	15,61	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Somnolence	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9552	0,92	0,06	14,78	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Tension headache	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Transient ischaemic attack	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Upper motor neurone lesion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Vocal cord paralysis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	4	6,5	58	93,5	0,9410	1,05	0,26	4,21	Convergence criterion (GCONV=1E-8) satisfied.	0,4307
Psychiatric disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,2257	3,72	0,38	36,30	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Psychiatric disorders	Anxiety	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Depressed mood	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5355	2,10	0,19	23,16	Convergence criterion (GCONV=1E-8) satisfied.	0,1908
Psychiatric disorders	Depression	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Insomnia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Psychiatric disorders	Insomnia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3270	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Mental status changes	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3297	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Psychiatric symptom	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Sleep disorder	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	2	3,2	60	96,8	0,6108	1,59	0,26	9,49	Convergence criterion (GCONV=1E-8) satisfied.	0,9958

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6368	1,54	0,26	9,24	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Acute kidney injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1462	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0952
Renal and urinary disorders	Dysuria	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Lower urinary tract symptoms	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Micturition disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Micturition disorder	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3017	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Pollakiuria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Proteinuria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Renal cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Renal impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Urinary tract pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5451	2,06	0,19	22,78	Convergence criterion (GCONV=1E-8) satisfied.	0,6809
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9651	0,94	0,06	15,03	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Balanoposthitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Breast discharge	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Breast pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Gynaecomastia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	17	26,6	47	73,4	62	61,4	11	17,7	51	82,3	0,1292	1,81	0,83	3,95	Convergence criterion (GCONV=1E-8) satisfied.	0,8891
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	14	35,0	26	65,0	39	38,6	9	23,1	30	76,9	0,1900	1,74	0,75	4,04	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Catarrh	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	< 65	64	61,5	7	10,9	57	89,1	62	61,4	6	9,7	56	90,3	0,6438	1,30	0,43	3,94	Convergence criterion (GCONV=1E-8) satisfied.	0,5121
Respiratory, thoracic and mediastinal disorders	Cough	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	4	10,3	35	89,7	0,2384	2,03	0,61	6,74	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dysphonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	4	6,3	60	93,8	62	61,4	2	3,2	60	96,8	0,2492	2,74	0,47	16,08	Convergence criterion (GCONV=1E-8) satisfied.	0,7195
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	3	7,7	36	92,3	0,6588	1,40	0,31	6,25	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3121	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Haemoptysis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Laryngospasm	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Lung disorder	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Nasal congestion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	< 65	64	61,5	3	4,7	61	95,3	62	61,4	2	3,2	60	96,8	0,6158	1,57	0,26	9,43	Convergence criterion (GCONV=1E-8) satisfied.	0,9967

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pleurisy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,0292	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1546	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1439	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Productive cough	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1374	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Rales	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Rales	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1554	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0805	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	16	25,0	48	75,0	62	61,4	2	3,2	60	96,8	0,0003	9,45	2,17	41,17	Convergence criterion (GCONV=1E-8) satisfied.	0,6620
Skin and subcutaneous tissue disorders		>= 65	40	38,5	20	50,0	20	50,0	39	38,6	4	10,3	35	89,7	<.0001	6,45	2,20	18,91	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Actinic keratosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9877	1,02	0,06	16,36	Convergence criterion (GCONV=1E-8) satisfied.	0,7070
Skin and subcutaneous tissue disorders	Alopecia	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5411	2,08	0,19	22,97	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Dermatitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis acneiform	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3213	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1427	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Drug eruption	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Dry skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Erythema	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Miliaria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3245	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Onychoclasia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Papule	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Pruritus	< 65	64	61,5	6	9,4	58	90,6	62	61,4	1	1,6	61	98,4	0,0437	6,60	0,79	54,81	Convergence criterion (GCONV=1E-8) satisfied.	0,9815
Skin and subcutaneous tissue disorders	Pruritus	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	1	2,6	38	97,4	0,0506	6,30	0,76	52,34	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Skin and subcutaneous tissue disorders	Psoriasis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3101	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0225	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0863	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash erythematous	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash maculopapular	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash pruritic	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Scar pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Skin burning sensation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Skin exfoliation	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Toxic skin eruption	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Toxic skin eruption	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Urticaria	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Vitiligo	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Surgical and medical procedures		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Surgical and medical procedures	Cancer surgery	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9698	1,04	0,15	7,38	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	3	7,7	36	92,3	0,9558	1,05	0,21	5,19	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hot flush	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders	Hypertension	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1377	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypotension	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Orthostatic hypotension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Orthostatic hypotension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Phlebitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Phlebitis superficial	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Vascular stenosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3110	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0470
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	6	9,2	59	90,8	68	67,3	7	10,3	61	89,7	0,9304	0,95	0,32	2,84	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1164
Blood and lymphatic system disorders	Anaemia	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	7	10,3	61	89,7	0,6845	0,79	0,25	2,49	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1208	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Lymphadenopathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2834
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1995	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	0	0,0	68	100,0	0,0304	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure chronic	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Metabolic cardiomyopathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Metabolic cardiomyopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Palpitations	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3711	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Sinus bradycardia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Congenital, familial and genetic disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Congenital, familial and genetic disorders	Gilbert's syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8258
Ear and labyrinth disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9873	1,02	0,06	16,36	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	3	30,0	7	70,0	0,3203	0,34	0,03	3,23	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders	Ear discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Ear discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Tinnitus	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1695	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vertigo	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Vestibular ataxia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vestibular ataxia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Asia Pacific and Australia	29	27,9	5	17,2	24	82,8	23	22,8	1	4,3	22	95,7	0,1253	4,63	0,54	39,81	Convergence criterion (GCONV=1E-8) satisfied.	0,6384
Endocrine disorders		Europe and Middle East	65	62,5	10	15,4	55	84,6	68	67,3	1	1,5	67	98,5	0,0029	11,72	1,50	91,68	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Autoimmune thyroiditis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Autoimmune thyroiditis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6590	1,71	0,15	19,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9283
Endocrine disorders	Hyperthyroidism	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2750	3,29	0,34	31,62	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1853	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Hypothyroidism	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	0	0,0	68	100,0	0,0043	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	2	8,7	21	91,3	0,4951	1,79	0,33	9,78	Convergence criterion (GCONV=1E-8) satisfied.	0,9180
Eye disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	3	4,4	65	95,6	0,9091	1,10	0,22	5,44	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2664	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Blepharitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1723
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1620	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Dry eye	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Eyelid oedema	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Ocular discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Ocular discomfort	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Retinal detachment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vision blurred	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Visual impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Visual impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous floaters	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	1	4,3	22	95,7	0,0333	6,98	0,87	55,94	Convergence criterion (GCONV=1E-8) satisfied.	0,2981
Gastrointestinal disorders		Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	8	11,8	60	88,2	0,3340	1,56	0,63	3,89	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	4	40,0	6	60,0	10	9,9	2	20,0	8	80,0	0,2365	2,72	0,49	15,23	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal distension	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1319	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain lower	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2615	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3924
Gastrointestinal disorders	Abdominal pain upper	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain upper	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	0,9703	1,05	0,07	16,87	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Bowel movement irregularity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Cheilitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,7151
Gastrointestinal disorders	Constipation	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1242	4,79	0,53	43,27	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Diarrhoea	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	0	0,0	68	100,0	0,0352	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dry mouth	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dry mouth	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dyspepsia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dysphagia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Faeces soft	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Faeces soft	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Flatulence	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2516
Gastrointestinal disorders	Gastrooesophageal reflux disease	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Haemorrhoids	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Haemorrhoids	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Hyperaesthesia teeth	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Large intestine polyp	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3384	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Mouth ulceration	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Mouth ulceration	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9901
Gastrointestinal disorders	Nausea	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2829	3,23	0,34	31,05	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	North America	10	9,6	3	30,0	7	70,0	10	9,9	1	10,0	9	90,0	0,1919	4,08	0,42	39,81	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3545	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Stomatitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Toothache	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Toothache	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5749
Gastrointestinal disorders	Vomiting	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9477	1,10	0,07	17,58	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	7	24,1	22	75,9	23	22,8	1	4,3	22	95,7	0,0455	6,49	0,79	53,18	Convergence criterion (GCONV=1E-8) satisfied.	0,3687
General disorders and administration site conditions		Europe and Middle East	65	62,5	16	24,6	49	75,4	68	67,3	9	13,2	59	86,8	0,0767	2,06	0,91	4,67	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,9000	1,13	0,16	8,07	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Asthenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Asthenia	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	2	2,9	66	97,1	0,0224	4,99	1,08	23,12	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site haematoma	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Catheter site pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chest pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1714	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chills	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5187
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	2	2,9	66	97,1	0,9700	1,04	0,15	7,37	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Gait disturbance	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3449	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1709	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Oedema peripheral	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4009
General disorders and administration site conditions	Oedema peripheral	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1294	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	1,0000	1,00	0,06	15,99	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Peripheral swelling	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Peripheral swelling	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	0	0,0	23	100,0	0,0222	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0194	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5064
Hepatobiliary disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,4957	2,25	0,20	24,87	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2794
Hepatobiliary disorders	Hepatic steatosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hyperbilirubin aemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1316	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitiviti	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitiviti	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitiviti	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Sarcoidosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Sarcoidosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Asia Pacific and Australia	29	27,9	17	58,6	12	41,4	23	22,8	6	26,1	17	73,9	0,0152	3,01	1,18	7,65	Convergence criterion (GCONV=1E-8) satisfied.	0,1184
Infections and infestations		Europe and Middle East	65	62,5	26	40,0	39	60,0	68	67,3	24	35,3	44	64,7	0,2362	1,40	0,80	2,44	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		North America	10	9,6	2	20,0	8	80,0	10	9,9	4	40,0	6	60,0	0,4385	0,51	0,09	2,85	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0990
Infections and infestations	Bronchitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	4	5,9	64	94,1	0,0549	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Candida infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Conjunctivitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cystitis	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1526	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Empyema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3304	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Fungal pharyngitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Furuncle	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Gastroenteritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastrointestinal bacterial overgrowth	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Herpes zoster	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Infectious pleural effusion	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4351

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Influenza	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5823	1,64	0,27	9,84	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Laryngitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	3	13,0	20	87,0	0,8248	1,18	0,26	5,30	Convergence criterion (GCONV=1E-8) satisfied.	0,5425
Infections and infestations	Nasopharyngitis	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	10	14,7	58	85,3	0,1374	0,43	0,13	1,36	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Oral fungal infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral herpes	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis externa	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis media	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Paronychia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8384	0,82	0,11	5,79	Convergence criterion (GCONV=1E-8) satisfied.	0,9890
Infections and infestations	Pharyngitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9717	1,05	0,07	16,81	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1104	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3726
Infections and infestations	Pneumonia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9476	1,10	0,07	17,56	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia pneumococcal	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Prostate infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pulpitis dental	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Respiratory tract infection	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5614	1,69	0,28	10,12	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Respiratory tract infection viral	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Rhinitis	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1455	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sinusitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Skin infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tinea infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tooth abscess	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3304	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tracheitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	3	13,0	20	87,0	0,5130	0,55	0,09	3,32	Convergence criterion (GCONV=1E-8) satisfied.	0,1354
Infections and infestations	Upper respiratory tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Urinary tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6420	0,57	0,05	6,29	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Vaginal infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Viral infection	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1452	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Viral upper respiratory tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	3	13,0	20	87,0	0,5176	0,56	0,09	3,34	Convergence criterion (GCONV=1E-8) satisfied.	0,1612
Injury, poisoning and procedural complications		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1506	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4523	2,44	0,22	26,91	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Contusion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Contusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Eye contusion	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1199
Injury, poisoning and procedural complications	Fall	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Fall	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Fracture	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	Asia Pacific and Austral- ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Joint dislocation	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Joint dislocation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2180
Injury, poisoning and procedural complications	Ligament sprain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Limb injury	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Limb injury	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Rib fracture	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Austral- ia	29	27,9	9	31,0	20	69,0	23	22,8	4	17,4	19	82,6	0,2223	2,05	0,63	6,67	Convergence criterion (GCONV=1E-8) satisfied.	0,1829
Investigations		Europe and Middle East	65	62,5	21	32,3	44	67,7	68	67,3	5	7,4	63	92,6	0,0001	5,45	2,05	14,50	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8736	0,85	0,12	6,06	Convergence criterion (GCONV=1E-8) satisfied.	0,2896
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	1	1,5	67	98,5	0,0865	5,34	0,62	45,69	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9065	0,85	0,05	13,56	Convergence criterion (GCONV=1E-8) satisfied.	0,5306
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,6006	1,61	0,27	9,62	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood alkaline phosphatase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1430	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood cholesterol increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood cholesterol increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1961	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine phosphokinase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood creatinine increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4867
Investigations	Blood creatinine increased	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1299	4,66	0,52	41,68	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0559	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood iron decreased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1526	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood lactate dehydrogenase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood magnesium decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood magnesium decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood pressure increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood thyroid stimulating hormone decreased	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0621	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood thyroid stimulating hormone decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood triglycerides increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood uric acid increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5356	2,10	0,19	23,15	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Creatinine renal clearance decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gastric pH decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	International normalised ratio increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,1824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Liver function test increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8896	0,82	0,05	13,15	Convergence criterion (GCONV=1E-8) satisfied.	0,6377
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Oxygen saturation decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Transaminases increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Urine bilirubin increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Weight decreased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,0583	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6498	1,73	0,16	19,11	Convergence criterion (GCONV=1E-8) satisfied.	0,3933
Investigations	Weight increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1225	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	5	17,2	24	82,8	23	22,8	2	8,7	21	91,3	0,3852	2,04	0,39	10,56	Convergence criterion (GCONV=1E-8) satisfied.	0,9089
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	12	18,5	53	81,5	68	67,3	9	13,2	59	86,8	0,3889	1,46	0,61	3,46	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5176	2,17	0,20	23,92	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Metabolism and nutrition disorders	Decreased appetite	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Decreased appetite	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,3024	3,10	0,32	29,76	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Dehydration	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1208	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypercholesterolaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1746	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Metabolism and nutrition disorders	Hyperglycaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2615	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3607
Metabolism and nutrition disorders	Hyperglycaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5206	2,15	0,20	23,77	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1431	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6425
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9604	1,07	0,07	17,16	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hyperuricaemia	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6858	1,63	0,15	18,02	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperuricaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypoglycaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Austral ia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1882	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1438	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypomagnesaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2488
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypovolaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypovolaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3428	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Iron deficiency	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Vitamin D deficiency	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3361	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	9	31,0	20	69,0	23	22,8	4	17,4	19	82,6	0,1669	2,25	0,69	7,33	Convergence criterion (GCONV=1E-8) satisfied.	0,0914
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	18	27,7	47	72,3	68	67,3	12	17,6	56	82,4	0,1243	1,77	0,85	3,68	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0185	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9027	0,84	0,05	13,45	Convergence criterion (GCONV=1E-8) satisfied.	0,2095
Musculoskeletal and connective tissue disorders	Arthralgia	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	4	5,9	64	94,1	0,1043	2,56	0,79	8,34	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0494	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2814

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8840	0,81	0,05	13,01	Convergence criterion (GCONV=1E-8) satisfied.	0,3637
Musculoskeletal and connective tissue disorders	Back pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	4	5,9	64	94,1	0,5786	0,62	0,11	3,43	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2799
Musculoskeletal and connective tissue disorders	Bone pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3306	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Bone pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Coccydynia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9632	1,07	0,07	17,08	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Limb discomfort	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle fatigue	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2010	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1209	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6838
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5929	1,62	0,27	9,71	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Neck pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3364	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2994	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6564	1,71	0,16	18,91	Convergence criterion (GCONV=1E-8) satisfied.	0,5862
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9787	1,04	0,06	16,60	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2963	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Periarthritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Periarthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Spinal pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Synovial cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Synovial cyst	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Tendonitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	2	8,7	21	91,3	0,4603	0,42	0,04	4,59	Convergence criterion (GCONV=1E-8) satisfied.	0,5367

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5361	2,10	0,19	23,13	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4429	2,48	0,22	27,41	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2664	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	2	8,7	21	91,3	0,4993	1,78	0,33	9,73	Convergence criterion (GCONV=1E-8) satisfied.	0,0857
Nervous system disorders		Europe and Middle East	65	62,5	15	23,1	50	76,9	68	67,3	18	26,5	50	73,5	0,5657	0,81	0,40	1,64	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		North America	10	9,6	7	70,0	3	30,0	10	9,9	3	30,0	7	70,0	0,0360	3,94	1,00	15,60	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Arachnoid cyst	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral arteriosclerosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cognitive disorder	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cognitive disorder	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Disturbance in attention	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9201	0,87	0,05	13,89	Convergence criterion (GCONV=1E-8) satisfied.	0,6538
Nervous system disorders	Dizziness	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1481	4,39	0,49	39,28	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dizziness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Dysaesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Encephalopathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9472
Nervous system disorders	Headache	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	3	4,4	65	95,6	0,7734	0,77	0,13	4,61	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Headache	North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,8985	1,14	0,16	8,09	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Hypoaesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1670	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Lethargy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Loss of consciousness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Memory impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Migraine	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Myelopathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Myelopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,7676
Nervous system disorders	Neuropathy peripheral	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	North America	10	9,6	4	40,0	6	60,0	10	9,9	1	10,0	9	90,0	0,0950	5,36	0,59	48,50	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Neurotoxicity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5726
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	3	4,4	65	95,6	0,7494	0,75	0,12	4,49	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Parosmia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4472
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9363	1,12	0,07	17,90	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Polyneuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1795	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Seizure	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Somnolence	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9702	1,05	0,07	16,86	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Somnolence	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2820
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Tension headache	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Transient ischaemic attack	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Transient ischaemic attack	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Upper motor neurone lesion	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Vocal cord paralysis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5515

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders		Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	4	5,9	64	94,1	0,8598	1,13	0,28	4,54	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4451	2,48	0,22	27,52	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Anxiety	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1396	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Depressed mood	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4199

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Depression	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6428	0,57	0,05	6,30	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Insomnia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Mental status changes	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders	Psychiatric symptom	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Sleep disorder	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1496
Renal and urinary disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	4	5,9	64	94,1	0,7923	0,82	0,18	3,66	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Acute kidney injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Acute kidney injury	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Dysuria	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9259	1,14	0,07	18,26	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Lower urinary tract symptoms	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Micturition disorder	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Pollakiuria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Proteinuria	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Proteinuria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal cyst	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3361	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Urinary tract pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Urinary tract pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0288
Reproductive system and breast disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0755	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Balanoposthitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Balanoposthitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast discharge	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3127	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Gynaecomastia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	12	41,4	17	58,6	23	22,8	2	8,7	21	91,3	0,0096	5,77	1,29	25,86	Convergence criterion (GCONV=1E-8) satisfied.	0,0684
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	16	24,6	49	75,4	68	67,3	13	19,1	55	80,9	0,2367	1,58	0,74	3,37	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	3	30,0	7	70,0	10	9,9	5	50,0	5	50,0	0,4497	0,58	0,14	2,43	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Catarrh	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	1	4,3	22	95,7	0,2562	3,31	0,37	29,62	Convergence criterion (GCONV=1E-8) satisfied.	0,7458
Respiratory, thoracic and mediastinal disorders	Cough	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	7	10,3	61	89,7	0,4162	1,51	0,55	4,12	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,9444	1,07	0,15	7,65	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dysphonia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9116	0,85	0,05	13,67	Convergence criterion (GCONV=1E-8) satisfied.	0,0608

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	2	2,9	66	97,1	0,0330	5,04	0,99	25,65	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Lung disorder	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3082	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3384	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6073

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	2	2,9	66	97,1	0,9343	1,09	0,15	7,71	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleurisy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1117	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,0168	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,0994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Productive cough	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rales	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3545	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3428	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	12	41,4	17	58,6	23	22,8	2	8,7	21	91,3	0,0060	6,28	1,40	28,12	Convergence criterion (GCONV=1E-8) satisfied.	0,5606
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	19	29,2	46	70,8	68	67,3	2	2,9	66	97,1	<.0001	11,86	2,76	50,95	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	5	50,0	5	50,0	10	9,9	2	20,0	8	80,0	0,0793	3,98	0,76	20,94	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Actinic keratosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Alopecia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9280
Skin and subcutaneous tissue disorders	Alopecia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9702	1,05	0,07	16,86	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4734	2,35	0,21	25,97	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3449	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1944	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2813	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Drug eruption	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dry skin	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0656	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Erythema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Erythema	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1435	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Miliaria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Onychoclasia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Papule	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Papule	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	1	4,3	22	95,7	0,0782	5,44	0,65	45,18	Convergence criterion (GCONV=1E-8) satisfied.	0,2274
Skin and subcutaneous tissue disorders	Pruritus	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0158	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	0,8996	1,20	0,07	19,14	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Psoriasis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3511	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1997	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0769	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0494	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash erythematous	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash maculopapular	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash maculopapular	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculopapular	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash pruritic	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Scar pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Skin burning sensation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin burning sensation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin exfoliation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Toxic skin eruption	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Urticaria	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Urticaria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Vitiligo	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Surgical and medical procedures		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures	Cancer surgery	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1844	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1455
Vascular disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	4	5,9	64	94,1	0,7917	0,82	0,18	3,65	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Vascular disorders	Hot flush	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1844	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1385	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypotension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Orthostatic hypotension	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis superficial	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Vascular stenosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	4	12,9	27	87,1	33	32,7	3	9,1	30	90,9	0,5656	1,55	0,35	6,91	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Blood and lymphatic system disorders		IIB	27	26,0	3	11,1	24	88,9	15	14,9	1	6,7	14	93,3	0,6487	1,68	0,17	16,18	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	3	5,7	50	94,3	0,4909	1,68	0,38	7,53	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	3	9,1	30	90,9	0,8656	1,15	0,23	5,69	Convergence criterion (GCONV=1E-8) satisfied.	0,9940
Blood and lymphatic system disorders	Anaemia	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9439	1,09	0,10	12,03	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	3	5,7	50	94,3	0,7865	1,25	0,25	6,19	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Lymphadenopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9361	1,12	0,07	17,93	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Cardiac failure	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure chronic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Metabolic cardiomyopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Palpitations	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Sinus bradycardia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Congenital, familial and genetic disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Congenital, familial and genetic disorders	Gilbert's syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1707	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0957
Ear and labyrinth disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4352	2,52	0,23	27,77	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Ear discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders	Tinnitus	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vertigo	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vestibular ataxia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	8	25,8	23	74,2	33	32,7	2	6,1	31	93,9	0,0201	5,20	1,10	24,50	Convergence criterion (GCONV=1E-8) satisfied.	0,3192

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	0	0,0	15	100,0	0,1167	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Autoimmune thyroiditis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9002	1,13	0,16	8,06	Convergence criterion (GCONV=1E-8) satisfied.	0,2164
Endocrine disorders	Hyperthyroidism	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	IIA	31	29,8	5	16,1	26	83,9	33	32,7	0	0,0	33	100,0	0,0130	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Endocrine disorders	Hypothyroidism	IIB	27	26,0	4	14,8	23	85,2	15	14,9	0	0,0	15	100,0	0,1167	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	5	16,1	26	83,9	33	32,7	2	6,1	31	93,9	0,1802	2,92	0,57	15,04	Convergence criterion (GCONV=1E-8) satisfied.	0,2549
Eye disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	3	5,7	50	94,3	0,4671	0,44	0,05	4,25	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Blepharitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Blepharitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9642	1,07	0,07	17,04	Convergence criterion (GCONV=1E-8) satisfied.	0,6082
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Dry eye	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Eyelid oedema	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Eyelid oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Ocular discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Retinal detachment	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Eye disorders	Vision blurred	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1228	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vision blurred	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Visual impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous floaters	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	7	22,6	24	77,4	33	32,7	4	12,1	29	87,9	0,2667	1,98	0,58	6,77	Convergence criterion (GCONV=1E-8) satisfied.	0,0382
Gastrointestinal disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	4	26,7	11	73,3	0,3714	0,54	0,13	2,15	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	12	26,1	34	73,9	53	52,5	3	5,7	50	94,3	0,0024	5,74	1,61	20,42	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal distension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4450	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain lower	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain upper	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3271
Gastrointestinal disorders	Abdominal pain upper	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9065	1,18	0,07	18,88	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Bowel movement irregularity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Cheilitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9642	1,07	0,07	17,04	Convergence criterion (GCONV=1E-8) satisfied.	0,2034
Gastrointestinal disorders	Constipation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Diarrhoea	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1865	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Gastrointestinal disorders	Dry mouth	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dry mouth	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dyspepsia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dysphagia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1797	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Faeces soft	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Faeces soft	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Flatulence	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2390
Gastrointestinal disorders	Gastrooesophageal reflux disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Haemorrhoids	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Haemorrhoids	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Hyperaesthesia teeth	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Large intestine polyp	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Mouth ulceration	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Mouth ulceration	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9173	1,16	0,07	18,52	Convergence criterion (GCONV=1E-8) satisfied.	0,1005
Gastrointestinal disorders	Nausea	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6452	0,53	0,03	8,43	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0271	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Stomatitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Gastrointestinal disorders	Toothache	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Toothache	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0734
Gastrointestinal disorders	Vomiting	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1814	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIA	31	29,8	9	29,0	22	71,0	33	32,7	5	15,2	28	84,8	0,1409	2,23	0,75	6,67	Convergence criterion (GCONV=1E-8) satisfied.	0,9788
General disorders and administration site conditions		IIB	27	26,0	5	18,5	22	81,5	15	14,9	1	6,7	14	93,3	0,3038	2,93	0,34	25,08	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions		IIIA	46	44,2	11	23,9	35	76,1	53	52,5	6	11,3	47	88,7	0,0704	2,43	0,90	6,59	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	2	6,1	31	93,9	0,5681	1,68	0,28	10,09	Convergence criterion (GCONV=1E-8) satisfied.	0,1985
General disorders and administration site conditions	Asthenia	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site haematoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Catheter site haematoma	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Chest discomfort	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2021	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chills	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Chills	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1717	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0375
General disorders and administration site conditions	Fatigue	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1167	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Gait disturbance	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Gait disturbance	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3785	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2072	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0550
General disorders and administration site conditions	Oedema peripheral	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1074	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Peripheral swelling	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIA	31	29,8	4	12,9	27	87,1	33	32,7	0	0,0	33	100,0	0,0343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Pyrexia	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	0	0,0	53	100,0	0,0064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0588
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0096	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2390
Hepatobiliary disorders	Hepatic steatosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Hepatobiliary disorders	Hyperbilirubinemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubinemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2854	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Immune system disorders	Sarcoidosis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	17	54,8	14	45,2	33	32,7	12	36,4	21	63,6	0,0819	1,91	0,91	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,3425
Infections and infestations		IIB	27	26,0	9	33,3	18	66,7	15	14,9	7	46,7	8	53,3	0,6674	0,80	0,30	2,18	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	19	41,3	27	58,7	53	52,5	15	28,3	38	71,7	0,0709	1,86	0,94	3,67	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4940
Infections and infestations	Bronchitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6543	0,54	0,03	8,60	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2036	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Candida infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Conjunctivitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cystitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Empyema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Fungal pharyngitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Furuncle	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Gastroenteritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastrointestinal bacterial overgrowth	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3810	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Herpes zoster	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Infectious pleural effusion	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2774	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,8923	1,14	0,16	8,14	Convergence criterion (GCONV=1E-8) satisfied.	0,3413

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Influenza	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3537	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Laryngitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3849	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngiti- s	IIA	31	29,8	1	3,2	30	96,8	33	32,7	6	18,2	27	81,8	0,0705	0,18	0,02	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,1172
Infections and infestations	Nasopharyngiti- s	IIB	27	26,0	2	7,4	25	92,6	15	14,9	3	20,0	12	80,0	0,2497	0,36	0,06	2,19	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngiti- s	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	4	7,5	49	92,5	0,4315	1,69	0,45	6,28	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Oral fungal infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral herpes	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis externa	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis media	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2519	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Paronychia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	2	6,1	31	93,9	0,6311	0,56	0,05	6,18	Convergence criterion (GCONV=1E-8) satisfied.	0,5685
Infections and infestations	Pharyngitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9140	1,16	0,07	18,62	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0656	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3468
Infections and infestations	Pneumonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8691	1,26	0,08	20,23	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia pneumococcal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2817	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Prostate infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pulpitis dental	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1240	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1141

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Respiratory tract infection	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6815	0,56	0,04	9,02	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Respiratory tract infection viral	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1086	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1401	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Rhinitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sinusitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Skin infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Tinea infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tooth abscess	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Tooth infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tracheitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9074	1,12	0,16	7,98	Convergence criterion (GCONV=1E-8) satisfied.	0,7956
Infections and infestations	Upper respiratory tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	3	5,7	50	94,3	0,4413	0,42	0,04	4,06	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1101

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Urinary tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1814	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3827	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Vaginal infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Viral infection	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Viral upper respiratory tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		IIA	31	29,8	3	9,7	28	90,3	33	32,7	2	6,1	31	93,9	0,5795	1,65	0,28	9,88	Convergence criterion (GCONV=1E-8) satisfied.	0,1735
Injury, poisoning and procedural complications		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2002	3,94	0,41	37,91	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Contusion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Eye contusion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Fall	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4206	2,59	0,23	28,59	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Fracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Joint dislocation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9419	1,11	0,07	17,73	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Ligament sprain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Limb injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Rib fracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	7	22,6	24	77,4	33	32,7	7	21,2	26	78,8	0,8303	1,12	0,39	3,20	Convergence criterion (GCONV=1E-8) satisfied.	0,0020

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		IIB	27	26,0	7	25,9	20	74,1	15	14,9	0	0,0	15	100,0	0,0202	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	20	43,5	26	56,5	53	52,5	2	3,8	51	96,2	<.0001	15,26	3,56	65,43	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIA	31	29,8	3	9,7	28	90,3	33	32,7	3	9,1	30	90,9	0,9177	1,09	0,22	5,39	Convergence criterion (GCONV=1E-8) satisfied.	0,0857
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0131	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	2	6,5	29	93,5	33	32,7	3	9,1	30	90,9	0,7240	0,73	0,12	4,34	Convergence criterion (GCONV=1E-8) satisfied.	0,1263
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood alkaline phosphatase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood cholesterol increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood creatine phosphokinase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1202	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,4743	2,34	0,21	25,82	Convergence criterion (GCONV=1E-8) satisfied.	0,2478
Investigations	Blood creatinine increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	0	0,0	53	100,0	0,0052	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood iron decreased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood lactate dehydrogenase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood magnesium decreased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood pressure increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3833	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Investigations	Blood thyroid stimulating hormone decreased	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2730	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood triglycerides increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9731	1,05	0,07	16,78	Convergence criterion (GCONV=1E-8) satisfied.	0,5685
Investigations	Blood uric acid increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2817	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Creatinine renal clearance decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2827	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gastric pH decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	International normalised ratio increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Liver function test increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5751
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9065	1,18	0,07	18,88	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Oxygen saturation decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Transaminases increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2620	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Urine bilirubin increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Weight decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,0500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0594
Investigations	Weight increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0093	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	4	12,9	27	87,1	33	32,7	5	15,2	28	84,8	0,8434	0,88	0,24	3,26	Convergence criterion (GCONV=1E-8) satisfied.	0,5839
Metabolism and nutrition disorders		IIB	27	26,0	7	25,9	20	74,1	15	14,9	2	13,3	13	86,7	0,3668	2,03	0,42	9,79	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	8	17,4	38	82,6	53	52,5	5	9,4	48	90,6	0,2281	1,96	0,64	6,00	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8326

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Decreased appetite	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4650	2,38	0,22	26,26	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Dehydration	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1823	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypercholesterolaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9316	1,13	0,07	18,05	Convergence criterion (GCONV=1E-8) satisfied.	0,9989

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hyperglycaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8875	1,22	0,08	19,54	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglycer idaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1738
Metabolism and nutrition disorders	Hypertriglycer idaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglycer idaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hyperuricaemia	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9421	1,09	0,10	12,05	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypoglycaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1347	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemi a	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypomagnesaemi a	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemi a	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphatae mia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphatae mia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphatae mia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8903	1,21	0,08	19,44	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypovolaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Iron deficiency	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Vitamin D deficiency	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeleta l and connective tissue disorders		IIA	31	29,8	7	22,6	24	77,4	33	32,7	6	18,2	27	81,8	0,5763	1,36	0,46	4,06	Convergence criterion (GCONV=1E-8) satisfied.	0,5042

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders		IIB	27	26,0	9	33,3	18	66,7	15	14,9	3	20,0	12	80,0	0,3535	1,84	0,50	6,82	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	15	32,6	31	67,4	53	52,5	7	13,2	46	86,8	0,0055	3,37	1,36	8,36	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	IIA	31	29,8	2	6,5	29	93,5	33	32,7	3	9,1	30	90,9	0,7446	0,74	0,12	4,45	Convergence criterion (GCONV=1E-8) satisfied.	0,2307
Musculoskeletal and connective tissue disorders	Arthralgia	IIB	27	26,0	6	22,2	21	77,8	15	14,9	1	6,7	14	93,3	0,1954	3,68	0,44	30,61	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	1	1,9	52	98,1	0,0507	6,43	0,75	55,12	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3448
Musculoskeletal and connective tissue disorders	Arthritis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,5029	2,22	0,20	24,52	Convergence criterion (GCONV=1E-8) satisfied.	0,2527
Musculoskeletal and connective tissue disorders	Back pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	4	7,5	49	92,5	0,3341	0,35	0,04	3,21	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2291
Musculoskeletal and connective tissue disorders	Bone pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Coccydynia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Coccydynia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2329
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Limb discomfort	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle spasms	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2897	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	2	3,8	51	96,2	0,2726	2,51	0,46	13,69	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Neck pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2464	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9153	1,16	0,07	18,63	Convergence criterion (GCONV=1E-8) satisfied.	0,2339
Musculoskeletal and connective tissue disorders	Pain in extremity	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6754	0,56	0,03	8,92	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1099	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Periarthritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Spinal pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeleta l and connective tissue disorders	Synovial cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeleta l and connective tissue disorders	Synovial cyst	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeleta l and connective tissue disorders	Tendonitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeleta l and connective tissue disorders	Tendonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeleta l and connective tissue disorders	Tendonitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	1	3,2	30	96,8	33	32,7	3	9,1	30	90,9	0,3820	0,38	0,04	3,64	Convergence criterion (GCONV=1E-8) satisfied.	0,2091

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2873	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,3671	2,90	0,26	32,43	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	8	25,8	23	74,2	33	32,7	7	21,2	26	78,8	0,5871	1,32	0,48	3,65	Convergence criterion (GCONV=1E-8) satisfied.	0,7703
Nervous system disorders		IIB	27	26,0	7	25,9	20	74,1	15	14,9	3	20,0	12	80,0	0,5502	1,51	0,39	5,83	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		IIIA	46	44,2	11	23,9	35	76,1	53	52,5	13	24,5	40	75,5	0,8391	0,92	0,40	2,10	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Arachnoid cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral arteriosclerosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cognitive disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Cognitive disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Disturbance in attention	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1640
Nervous system disorders	Dizziness	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Dizziness	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4387	2,50	0,23	27,58	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Dysaesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Encephalopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,8858	1,15	0,16	8,20	Convergence criterion (GCONV=1E-8) satisfied.	0,6257
Nervous system disorders	Headache	IIB	27	26,0	1	3,7	26	96,3	15	14,9	2	13,3	13	86,7	0,2666	0,28	0,03	3,09	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Headache	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,8811	1,24	0,08	19,78	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Hypoaesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Lethargy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Loss of consciousness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Memory impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Migraine	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Myelopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Myelopathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	IIA	31	29,8	4	12,9	27	87,1	33	32,7	0	0,0	33	100,0	0,0311	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2476
Nervous system disorders	Neuropathy peripheral	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8656	1,27	0,08	20,37	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Neurotoxicity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4131
Nervous system disorders	Paraesthesia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Paraesthesia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	4	7,5	49	92,5	0,2595	0,30	0,03	2,72	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3074	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Parosmia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8280
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4492	2,45	0,22	27,04	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Polyneuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Seizure	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3456
Nervous system disorders	Somnolence	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Nervous system disorders	Somnolence	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9044	1,18	0,07	18,95	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Tension headache	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Transient ischaemic attack	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Nervous system disorders	Transient ischaemic attack	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Upper motor neurone lesion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Vocal cord paralysis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,7699	1,34	0,19	9,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9132
Psychiatric disorders		IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9086	1,15	0,10	12,70	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	2	3,8	51	96,2	0,4652	1,93	0,32	11,54	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,0733	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Anxiety	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2824	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Depressed mood	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,8866	1,22	0,08	19,56	Convergence criterion (GCONV=1E-8) satisfied.	0,9992
Psychiatric disorders	Depression	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Psychiatric disorders	Depression	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8603	1,28	0,08	20,50	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Insomnia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1090	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Mental status changes	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Psychiatric symptom	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders	Psychiatric symptom	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3833	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Sleep disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9458	1,10	0,07	18,02	Convergence criterion (GCONV=1E-8) satisfied.	0,7246
Renal and urinary disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	3	5,7	50	94,3	0,4702	1,73	0,39	7,73	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Acute kidney injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Acute kidney injury	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1085	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Dysuria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8585	1,29	0,08	20,62	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Lower urinary tract symptoms	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Micturition disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3827	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Pollakiuria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Proteinuria	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Proteinuria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Urinary tract pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Urinary tract pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2339
Reproductive system and breast disorders		IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9779	1,03	0,09	11,43	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthiti s	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Balanoposthiti s	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthiti s	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast discharge	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Reproductive system and breast disorders	Breast discharge	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Gynaecomastia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Reproductive system and breast disorders	Gynaecomastia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	13	41,9	18	58,1	33	32,7	7	21,2	26	78,8	0,0717	2,28	0,91	5,72	Convergence criterion (GCONV=1E-8) satisfied.	0,1596
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	4	26,7	11	73,3	0,3134	0,50	0,12	1,99	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	14	30,4	32	69,6	53	52,5	9	17,0	44	83,0	0,0336	2,52	1,04	6,09	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Catarrh	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	IIA	31	29,8	6	19,4	25	80,6	33	32,7	4	12,1	29	87,9	0,4015	1,71	0,48	6,06	Convergence criterion (GCONV=1E-8) satisfied.	0,4840
Respiratory, thoracic and mediastinal disorders	Cough	IIB	27	26,0	2	7,4	25	92,6	15	14,9	2	13,3	13	86,7	0,5213	0,53	0,07	3,78	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Cough	IIIA	46	44,2	7	15,2	39	84,8	53	52,5	4	7,5	49	92,5	0,1281	2,62	0,73	9,44	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	5	16,1	26	83,9	33	32,7	0	0,0	33	100,0	0,0144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0034
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	2	13,3	13	86,7	0,0582	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	3	5,7	50	94,3	0,5914	1,56	0,30	8,10	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0988
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6856	0,57	0,04	9,09	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1166	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0669	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Productive cough	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Productive cough	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rales	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1290	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1349	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1139	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3771	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	11	35,5	20	64,5	33	32,7	2	6,1	31	93,9	0,0028	7,19	1,59	32,49	Convergence criterion (GCONV=1E-8) satisfied.	0,6755
Skin and subcutaneous tissue disorders		IIB	27	26,0	5	18,5	22	81,5	15	14,9	1	6,7	14	93,3	0,2700	3,14	0,37	26,90	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders		IIIA	46	44,2	20	43,5	26	56,5	53	52,5	3	5,7	50	94,3	<.0001	10,42	3,09	35,13	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Actinic keratosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3004
Skin and subcutaneous tissue disorders	Alopecia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2170	3,77	0,39	36,28	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Dermatitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3785	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2827	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2498	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Drug eruption	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Drug eruption	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dry skin	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1036	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Erythema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1177	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Miliaria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Miliaria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Onychoclasia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Papule	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0623	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3522
Skin and subcutaneous tissue disorders	Pruritus	IIB	27	26,0	3	11,1	24	88,9	15	14,9	1	6,7	14	93,3	0,6201	1,76	0,18	16,91	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	1	1,9	52	98,1	0,0211	8,10	0,97	67,31	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0676	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0262	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash erythematous	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash pruritic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Rash pruritic	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Scar pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin burning sensation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin exfoliation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Skin exfoliation	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Urticaria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Vitiligo	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Vitiligo	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures	Cancer surgery	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,5011	2,23	0,20	24,60	Convergence criterion (GCONV=1E-8) satisfied.	0,7119
Vascular disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6892	0,57	0,04	9,15	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Vascular disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	3	5,7	50	94,3	0,8446	0,84	0,14	5,01	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hot flush	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1280	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypotension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Vascular disorders	Hypotension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Orthostatic hypotension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis superficial	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Vascular disorders	Phlebitis superficial	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Vascular stenosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

All

		Atezolizumab (N=104)							Best Supportive Care(BSC) (N=101)							Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored			Patients		Patients with Event		Censored			log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)	
Blood and lymphatic system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Thrombocytope nia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Eye disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5720	0,51	0,05	5,59	Convergence criterion (GCONV=1E-8) satisfied.	NE	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9964	0,99	0,06	15,88	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5647	2,00	0,18	22,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Pyrexia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3001	3,11	0,32	29,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0260	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0397	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations		n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9914	0,99	0,14	7,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3266	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1546	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0,0	101	100,0	0,0234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphataemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,4748	2,36	0,21	26,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4177	0,50	0,09	2,74	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9941	1,01	0,06	16,16	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1788	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4932	0,44	0,04	4,88	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9321	0,89	0,06	14,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3839
General disorders and administrative site conditions		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7843	1,47	0,09	23,51	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administrative site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administrative site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3765	2,67	0,28	25,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0631	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Infections and infestations		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0631	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9960
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2539
Investigations		Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,7534	0,68	0,06	7,53	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2322	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1793	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,5484	2,06	0,18	23,09	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	3	4,2	68	95,8	0,2491	0,29	0,03	2,76	Convergence criterion (GCONV=1E-8) satisfied.	0,3594
Nervous system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7548	1,55	0,10	24,94	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1295
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Skin and subcutaneous tissue disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0778	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypertension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders	Hypertension	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 13:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1493	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Blood and lymphatic system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3160
Eye disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9913	1,02	0,06	16,24	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9732	1,05	0,07	16,77	Convergence criterion (GCONV=1E-8) satisfied.	0,3159
General disorders and administration site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5249	2,14	0,19	23,59	Convergence criterion (GCONV=1E-8) satisfied.	0,4248

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Infections and infestations		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5678	0,50	0,05	5,55	Convergence criterion (GCONV=1E-8) satisfied.	0,1942
Investigations		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1595	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0395	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1673	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9970	0,99	0,06	15,91	Convergence criterion (GCONV=1E-8) satisfied.	0,3080
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	3	4,8	59	95,2	0,3227	0,34	0,04	3,24	Convergence criterion (GCONV=1E-8) satisfied.	0,5524
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9961	0,99	0,06	15,92	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0943
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Skin and subcutaneous tissue disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypertension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System	MedDRA	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Organ Class	Preferred Term																			

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9033	0,84	0,05	13,47	Convergence criterion (GCONV=1E-8) satisfied.	0,6434
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2793
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5370	2,09	0,19	23,09	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4765
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9791	1,04	0,06	16,59	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3689
Investigations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5413	2,08	0,19	22,93	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1453	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6157

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9817	1,03	0,06	16,52	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8862	0,82	0,05	13,07	Convergence criterion (GCONV=1E-8) satisfied.	0,8955

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	3	4,4	65	95,6	0,3646	0,37	0,04	3,52	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2393
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1403	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sq_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1552
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2053	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2558
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4371	2,51	0,23	27,69	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Pyrexia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0949
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0466	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0184	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4105
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4709	2,36	0,21	25,97	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglycridaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglycridaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglycridaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1705
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6175
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	3	5,7	50	94,3	0,8201	0,81	0,14	4,87	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1661
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 13:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

All

		Atezolizumab (N=104)							Best Supportive Care(BSC) (N=101)							Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored			Patients		Patients with Event		Censored			log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)	
Blood and lymphatic system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Thrombocytope nia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Eye disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5720	0,51	0,05	5,59	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9964	0,99	0,06	15,88	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5647	2,00	0,18	22,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Pyrexia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3001	3,11	0,32	29,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0260	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0397	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5671	1,99	0,18	21,93	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3266	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0826	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphatemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,4748	2,36	0,21	26,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9979	1,00	0,14	7,08	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:55

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1788	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4932	0,44	0,04	4,88	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9321	0,89	0,06	14,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3839
General disorders and administrative site conditions		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7843	1,47	0,09	23,51	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administrative site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administrative site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Pyrexia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administrative site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3765	2,67	0,28	25,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0631	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Infections and infestations		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0631	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9960
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3815
Investigations		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8274	1,36	0,08	21,76	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1830	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Metabolism and nutrition disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphatemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1793	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,5484	2,06	0,18	23,09	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4842	0,43	0,04	4,80	Convergence criterion (GCONV=1E-8) satisfied.	0,1281
Nervous system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Skin and subcutaneous tissue disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0778	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders	Hypertension	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:55

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1493	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Blood and lymphatic system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3160
Eye disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9913	1,02	0,06	16,24	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9732	1,05	0,07	16,77	Convergence criterion (GCONV=1E-8) satisfied.	0,3159
General disorders and administration site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5249	2,14	0,19	23,59	Convergence criterion (GCONV=1E-8) satisfied.	0,4248
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Infections and infestations		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	1,0000	1,00	0,06	15,99	Convergence criterion (GCONV=1E-8) satisfied.	0,3086
Investigations		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Metabolism and nutrition disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1673	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9970	0,99	0,06	15,91	Convergence criterion (GCONV=1E-8) satisfied.	0,3080
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5649	0,50	0,05	5,53	Convergence criterion (GCONV=1E-8) satisfied.	0,1903
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Skin and subcutaneous tissue disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypertension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 13:55

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9033	0,84	0,05	13,47	Convergence criterion (GCONV=1E-8) satisfied.	0,6434
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2793

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5370	2,09	0,19	23,09	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4765
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9791	1,04	0,06	16,59	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Kidney infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1235
Investigations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1453	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6157
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9817	1,03	0,06	16,52	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4757
Nervous system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6116	0,54	0,05	5,98	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1403	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 13:55

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1552
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2053	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2558
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4371	2,51	0,23	27,69	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0949

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0466	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0184	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4709	2,36	0,21	25,97	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0519	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1705
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	2	3,8	51	96,2	0,8558	1,20	0,17	8,52	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

All

		Atezolizumab (N=104)							Best Supportive Care(BSC) (N=101)							Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored			Patients		Patients with Event		Censored			log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)	
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Investigations		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Metabolism and nutrition disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1520	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1676	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 14:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Investigations		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1775	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Metabolism and nutrition disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 14:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Metabolism and nutrition disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Nervous system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System	MedDRA Organ Class	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 14:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1104	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

All

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3226	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3226	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal hernia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Pyrexia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9807	1,03	0,06	16,54	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3066	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1582	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Sarcoidosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	7	6,7	97	93,3	101	100,0	0	0,0	101	100,0	0,0083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia pneumococcal	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3268	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tonsillitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9713	0,95	0,06	15,20	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3021	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6492	1,51	0,25	9,04	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral infarction	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Loss of consciousness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3149	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1635	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3198	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Psoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3198	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2817	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2817	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders	Abdominal hernia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1868	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1868	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9254	0,88	0,05	14,00	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1846	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Immune system disorders	Sarcoidosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Sarcoidosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0607	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Infections and infestations		Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0383	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3555	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia pneumococcal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Sepsis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Tonsillitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9052	0,85	0,05	13,51	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4863	0,44	0,04	4,82	Convergence criterion (GCONV=1E-8) satisfied.	0,0466
Nervous system disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3462	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Cerebral infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Loss of consciousness	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2842	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1886	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Psoriasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 14:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3251	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3251	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Atrial fibrillation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal hernia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administrative site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administrative site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0993
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1588	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Sarcoidosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0857	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Infections and infestations		>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia pneumococcal	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Sepsis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tonsillitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3074	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1006
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3074	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9991	1,00	0,14	7,09	Convergence criterion (GCONV=1E-8) satisfied.	0,2777
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral infarction	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Loss of consciousness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1627	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Psoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 14:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9507	1,09	0,07	17,46	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2884	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Sarcoidosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infestations and infections		Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3100	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sepsis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2343
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3126	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3126	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9218	0,87	0,05	13,92	Convergence criterion (GCONV=1E-8) satisfied.	0,8790
Nervous system disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5420	2,08	0,19	22,89	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Loss of consciousness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3364	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2983	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2983	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3749	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3749	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2296
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Sarcoidosis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Sarcoidosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	7	15,2	39	84,8	53	52,5	0	0,0	53	100,0	0,0034	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2877	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sepsis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2394
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2861
Nervous system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4703	2,36	0,21	26,02	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2568	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3482	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Psoriasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

Zum Behandlungsabbruch führende unerwünschte Ereignisse nach SOC/PT (deskriptiv)

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		n/a	104	100,0	2	1,9	101	100,0	0	0
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	1	1,0	101	100,0	0	0
Cardiac disorders	Cardiac failure	n/a	104	100,0	1	1,0	101	100,0	0	0
Endocrine disorders		n/a	104	100,0	2	1,9	101	100,0	0	0
Endocrine disorders	Hypothyroidism	n/a	104	100,0	2	1,9	101	100,0	0	0
Gastrointestin al disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Gastrointestin al disorders	Colitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	100,0	0	0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0
Immune system disorders		n/a	104	100,0	2	1,9	101	100,0	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	101	100,0	0	0
Immune system disorders	Sarcoidosis	n/a	104	100,0	1	1,0	101	100,0	0	0
Infections and infestations		n/a	104	100,0	2	1,9	101	100,0	0	0
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations		n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Alanine aminotransferase increased	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations	Blood creatinine increased	n/a	104	100,0	1	1,0	101	100,0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	1	1,0	101	100,0	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	5	4,8	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	3	2,9	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: AEs leading to Atezolizumab Discontinuation

MODEL: Unstratified analysis

STUDY: GO29527

Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		Male	82	78,8	2	2,4	71	70,3	0	0
Cardiac disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Cardiac disorders	Atrial fibrillation	Male	82	78,8	1	1,2	71	70,3	0	0
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	30	29,7	0	0
Cardiac disorders	Cardiac failure	Male	82	78,8	1	1,2	71	70,3	0	0
Cardiac disorders	Cardiac failure	Female	22	21,2	0	0,0	30	29,7	0	0
Endocrine disorders		Male	82	78,8	2	2,4	71	70,3	0	0
Endocrine disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Endocrine disorders	Hypothyroidism	Male	82	78,8	2	2,4	71	70,3	0	0
Endocrine disorders	Hypothyroidism	Female	22	21,2	0	0,0	30	29,7	0	0
Gastrointestin al disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Gastrointestin al disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Gastrointestin al disorders	Colitis	Male	82	78,8	1	1,2	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders		Male	82	78,8	3	3,7	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0
Immune system disorders		Male	82	78,8	2	2,4	71	70,3	0	0
Immune system disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	71	70,3	0	0
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	30	29,7	0	0
Immune system disorders	Sarcoidosis	Male	82	78,8	1	1,2	71	70,3	0	0
Immune system disorders	Sarcoidosis	Female	22	21,2	0	0,0	30	29,7	0	0
Infections and infestations		Male	82	78,8	0	0,0	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Infections and infestations		Female	22	21,2	2	9,1	30	29,7	0	0
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	71	70,3	0	0
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	30	29,7	0	0
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	71	70,3	0	0
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations		Male	82	78,8	1	1,2	71	70,3	0	0
Investigations		Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Alanine aminotransfera se increased	Male	82	78,8	0	0,0	71	70,3	0	0
Investigations	Alanine aminotransfera se increased	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Aspartate aminotransfera se increased	Male	82	78,8	0	0,0	71	70,3	0	0
Investigations	Aspartate aminotransfera se increased	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Blood creatinine increased	Male	82	78,8	1	1,2	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Blood creatinine increased	Female	22	21,2	0	0,0	30	29,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	1	1,2	71	70,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	30	29,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	71	70,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	5	6,1	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	30	29,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Male	82	78,8	1	1,2	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	3	3,7	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	0	0,0	30	29,7	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders		>= 65	40	38,5	2	5,0	39	38,6	0	0
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders	Atrial fibrillation	>= 65	40	38,5	1	2,5	39	38,6	0	0
Cardiac disorders	Cardiac failure	< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders	Cardiac failure	>= 65	40	38,5	1	2,5	39	38,6	0	0
Endocrine disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Endocrine disorders		>= 65	40	38,5	0	0,0	39	38,6	0	0
Endocrine disorders	Hypothyroidism	< 65	64	61,5	2	3,1	62	61,4	0	0
Endocrine disorders	Hypothyroidism	>= 65	40	38,5	0	0,0	39	38,6	0	0
Gastrointestinal disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Gastrointestinal disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	39	38,6	0	0
Immune system disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Immune system disorders		>= 65	40	38,5	0	0,0	39	38,6	0	0
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	62	61,4	0	0
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	39	38,6	0	0
Immune system disorders	Sarcoidosis	< 65	64	61,5	1	1,6	62	61,4	0	0
Immune system disorders	Sarcoidosis	>= 65	40	38,5	0	0,0	39	38,6	0	0
Infections and infestations		< 65	64	61,5	1	1,6	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Infections and infestations		>= 65	40	38,5	1	2,5	39	38,6	0	0
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	62	61,4	0	0
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	39	38,6	0	0
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	62	61,4	0	0
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	38,6	0	0
Investigations		< 65	64	61,5	2	3,1	62	61,4	0	0
Investigations		>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Alanine aminotransfera se increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Alanine aminotransfera se increased	>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Aspartate aminotransfera se increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Aspartate aminotransfera se increased	>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Blood creatinine increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Blood creatinine increased	>= 65	40	38,5	0	0,0	39	38,6	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	62	61,4	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	0	0,0	39	38,6	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	62	61,4	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	3	7,5	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	< 65	64	61,5	1	1,6	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	>= 65	40	38,5	0	0,0	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	1	1,6	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	2	5,0	39	38,6	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Cardiac disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Cardiac disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Cardiac disorders	Atrial fibrillation	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	9,9	0	0
Cardiac disorders	Cardiac failure	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders	Cardiac failure	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Cardiac disorders	Cardiac failure	North America	10	9,6	0	0,0	10	9,9	0	0
Endocrine disorders		Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Endocrine disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Endocrine disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Endocrine disorders	Hypothyroidism	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Endocrine disorders	Hypothyroidism	Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Endocrine disorders	Hypothyroidism	North America	10	9,6	0	0,0	10	9,9	0	0
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0
Immune system disorders		Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Immune system disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Immune system disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Immune system disorders	Hypersensitivi ty	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Immune system disorders	Hypersensitivi ty	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Immune system disorders	Hypersensitivi ty	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders	Sarcoidosis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Immune system disorders	Sarcoidosis	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Immune system disorders	Sarcoidosis	North America	10	9,6	0	0,0	10	9,9	0	0
Immune system disorders	Sarcoidosis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Immune system disorders	Sarcoidosis	Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Immune system disorders	Sarcoidosis	North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Infections and infestations		North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations	Encephalitis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Infections and infestations	Meningitis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations		North America	10	9,6	1	10,0	10	9,9	0	0
Investigations	Alanine aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Alanine aminotransfera se increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Alanine aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Aspartate aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Aspartate aminotransfera se increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Aspartate aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Blood creatinine increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Blood creatinine increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Investigations	Blood creatinine increased	North America	10	9,6	1	10,0	10	9,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	0	0,0	10	9,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Austral ia	29	27,9	3	10,3	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Austral ia	29	27,9	3	10,3	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Cardiac disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Cardiac disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	1	3,2	33	32,7	0	0
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	15	14,9	0	0
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	0	0,0	53	52,5	0	0
Cardiac disorders	Cardiac failure	IIA	31	29,8	0	0,0	33	32,7	0	0
Cardiac disorders	Cardiac failure	IIB	27	26,0	0	0,0	15	14,9	0	0
Cardiac disorders	Cardiac failure	IIIA	46	44,2	1	2,2	53	52,5	0	0
Endocrine disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Endocrine disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Endocrine disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Endocrine disorders	Hypothyroidism	IIA	31	29,8	1	3,2	33	32,7	0	0
Endocrine disorders	Hypothyroidism	IIB	27	26,0	0	0,0	15	14,9	0	0
Endocrine disorders	Hypothyroidism	IIIA	46	44,2	1	2,2	53	52,5	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Gastrointestinal disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	53	52,5	0	0
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	33	32,7	0	0
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	53	52,5	0	0
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Immune system disorders		IIB	27	26,0	1	3,7	15	14,9	0	0
Immune system disorders		IIIA	46	44,2	0	0,0	53	52,5	0	0
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	33	32,7	0	0
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	15	14,9	0	0
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	53	52,5	0	0
Immune system disorders	Sarcoidosis	IIA	31	29,8	0	0,0	33	32,7	0	0
Immune system disorders	Sarcoidosis	IIB	27	26,0	1	3,7	15	14,9	0	0
Immune system disorders	Sarcoidosis	IIIA	46	44,2	0	0,0	53	52,5	0	0
Infections and infestations		IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations		IIB	27	26,0	0	0,0	15	14,9	0	0
Infections and infestations		IIIA	46	44,2	2	4,3	53	52,5	0	0
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	15	14,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	53	52,5	0	0
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	53	52,5	0	0
Investigations		IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations		IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations		IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations	Alanine aminotransfera se increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Alanine aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Alanine aminotransfera se increased	IIIA	46	44,2	1	2,2	53	52,5	0	0
Investigations	Aspartate aminotransfera se increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Aspartate aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Aspartate aminotransfera se increased	IIIA	46	44,2	1	2,2	53	52,5	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Blood creatinine increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Blood creatinine increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Blood creatinine increased	IIIA	46	44,2	1	2,2	53	52,5	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	33	32,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	15	14,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	0	0,0	53	52,5	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	33	32,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	15	14,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	3	9,7	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	2	4,3	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIA	31	29,8	0	0,0	33	32,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIIA	46	44,2	1	2,2	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	3	9,7	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	0	0,0	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

KM Plots

Unstratifiziert

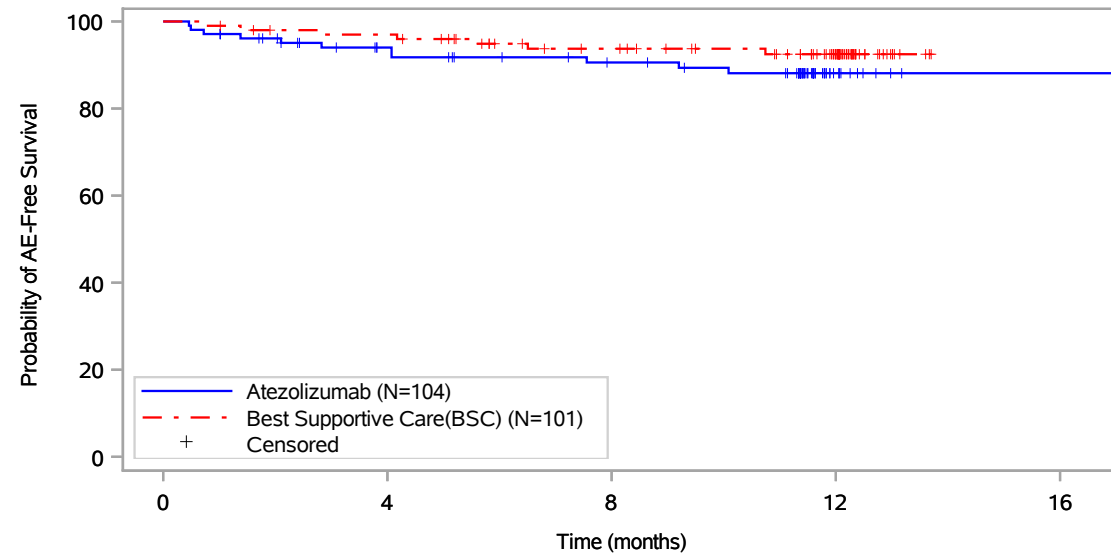
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, All



Patients at risk					
Atezolizumab (N=104)	104	84	75	11	1
Best Supportive Care(BSC) (N=101)	101	95	80	53	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	82	92
Best Supportive Care(BSC) (N=101)	0	3	15	41	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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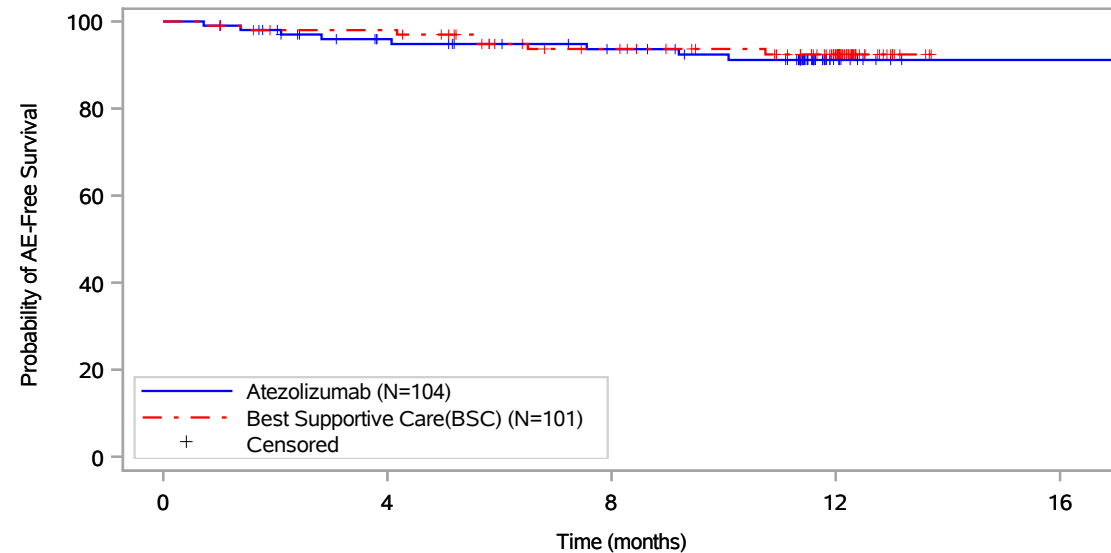
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Anaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	78	11	1
Best Supportive Care(BSC) (N=101)	101	96	80	53	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	85	95
Best Supportive Care(BSC) (N=101)	0	3	15	41	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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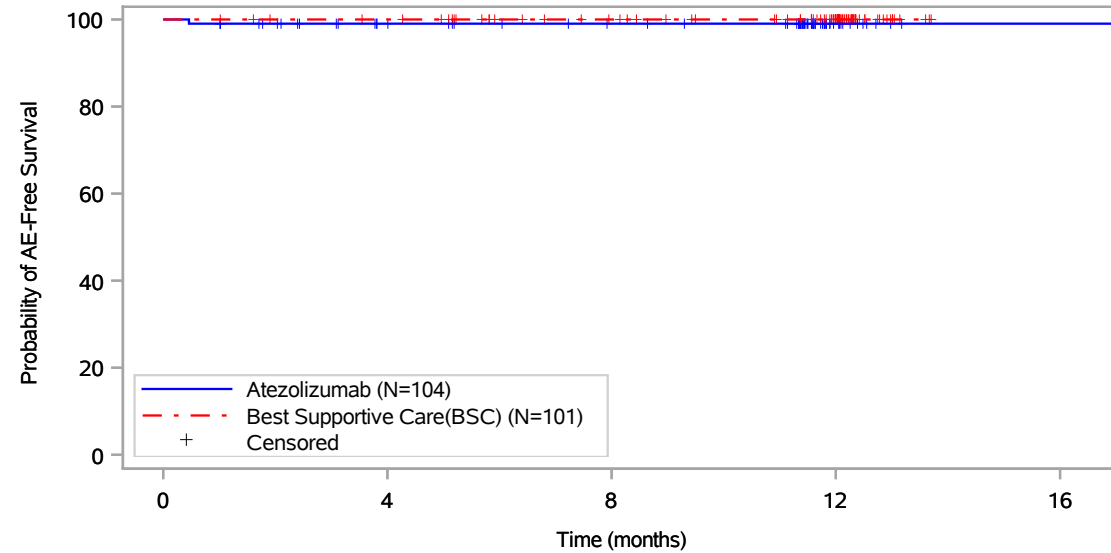
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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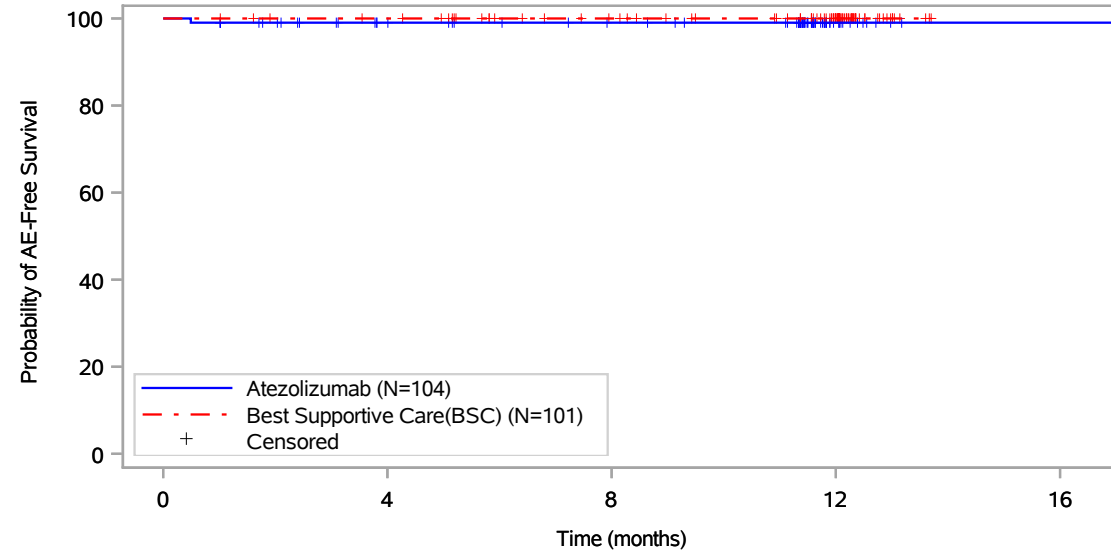
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Lymphadenopathy



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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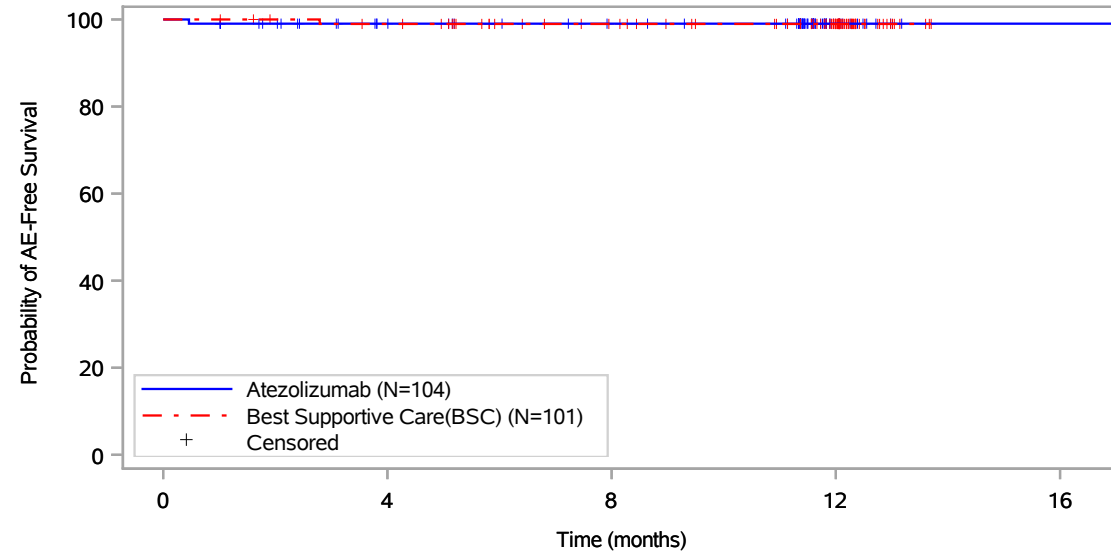
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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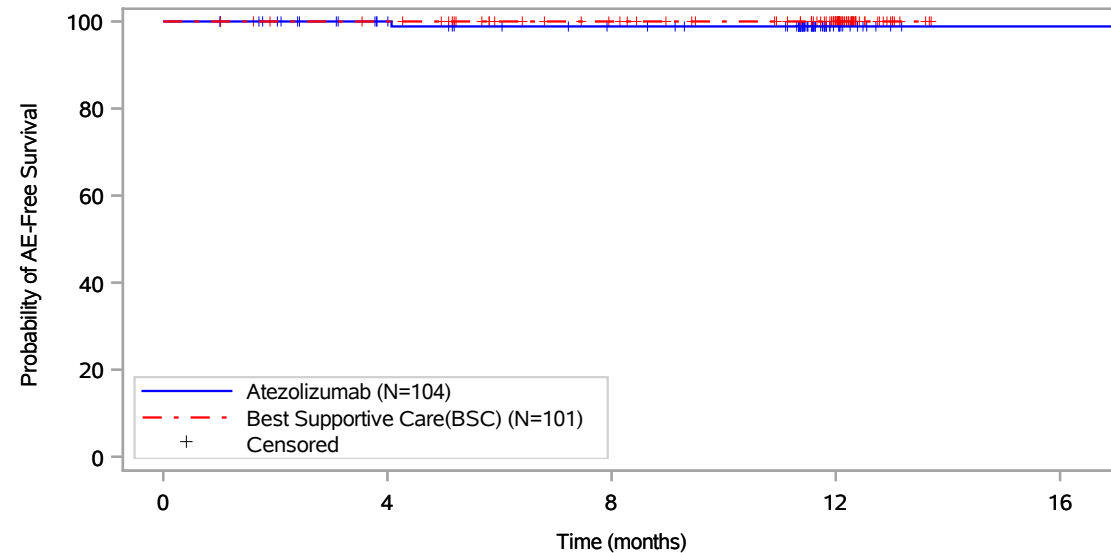
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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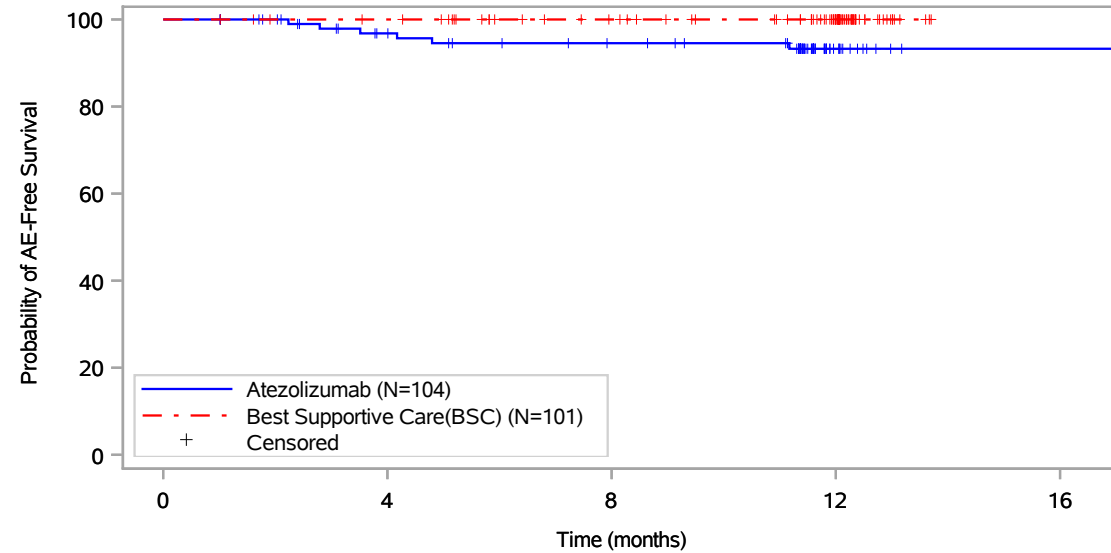
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, All



Patients at risk					
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	85	97
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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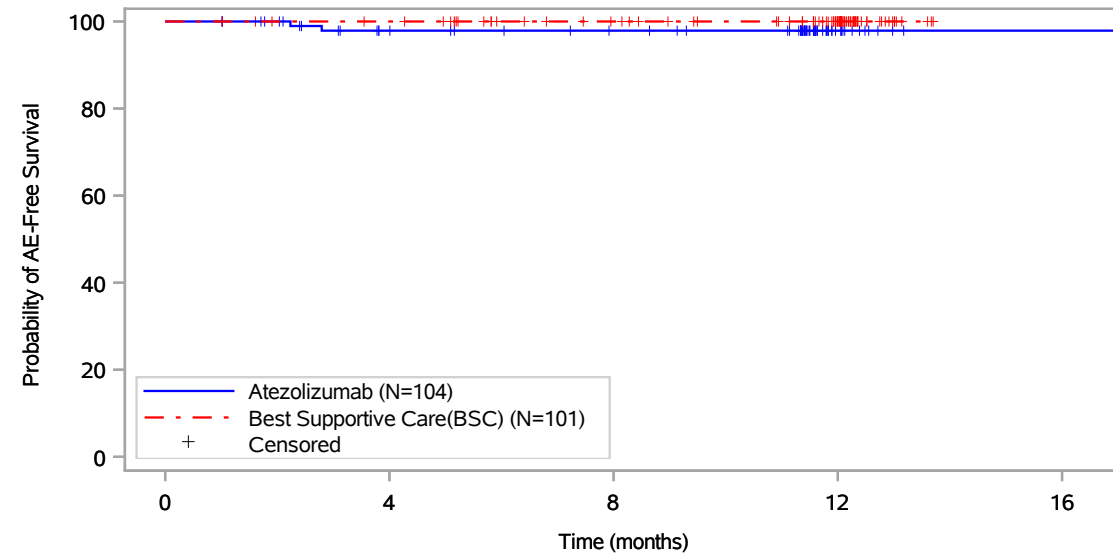
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Atrial fibrillation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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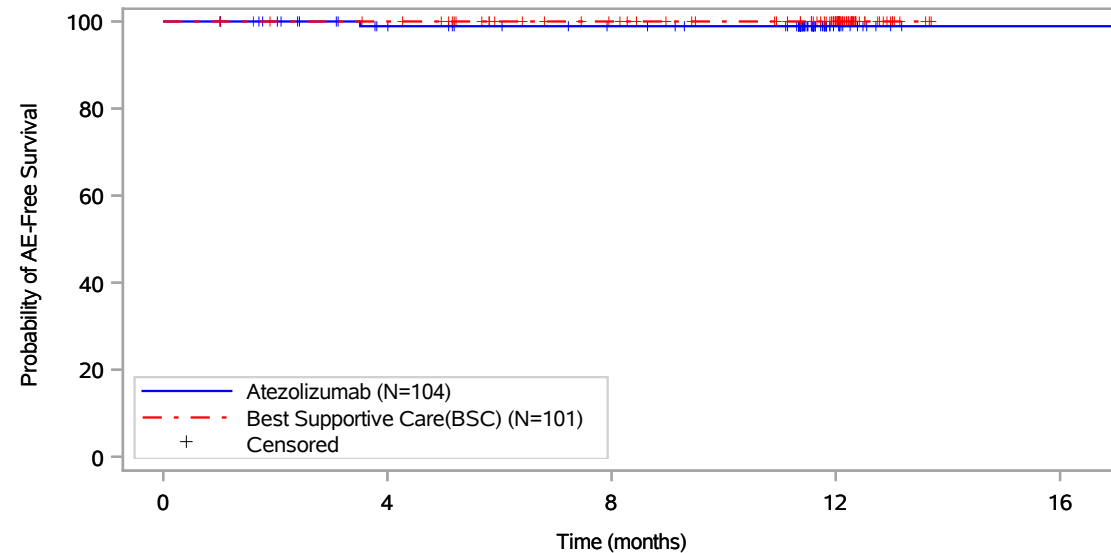
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Cardiac failure



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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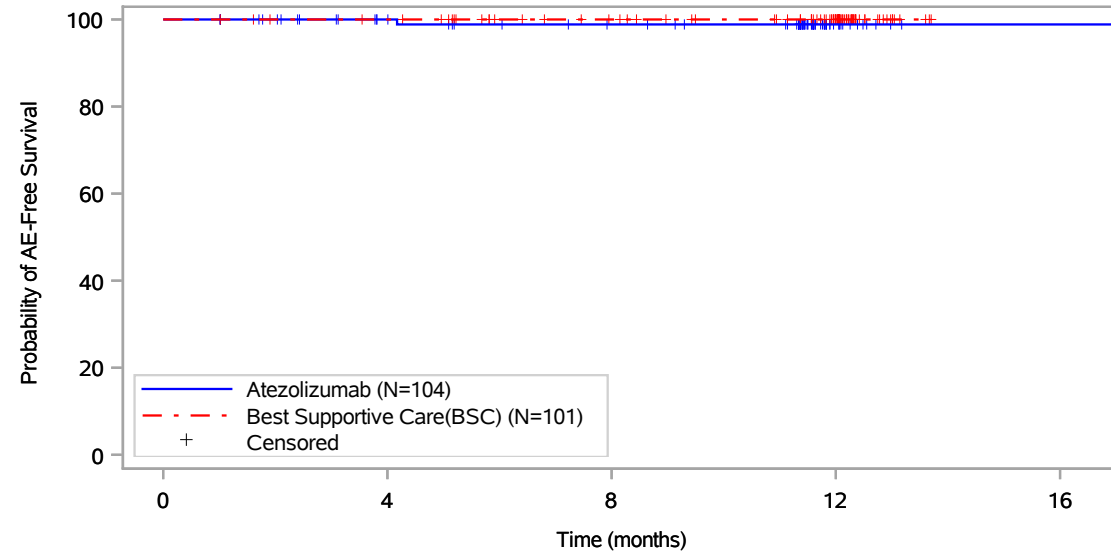
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Cardiac failure chronic



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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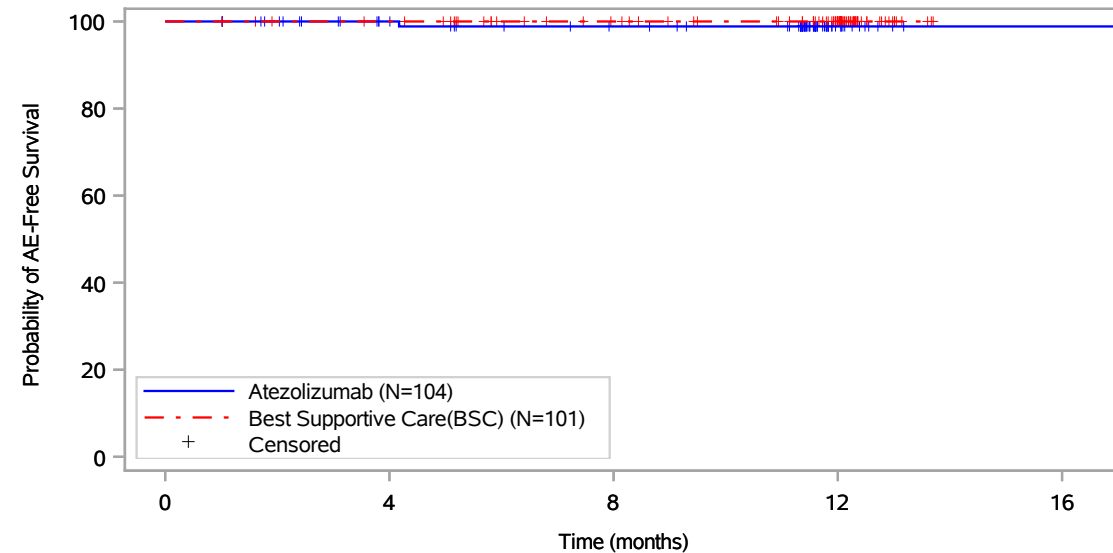
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Metabolic cardiomyopathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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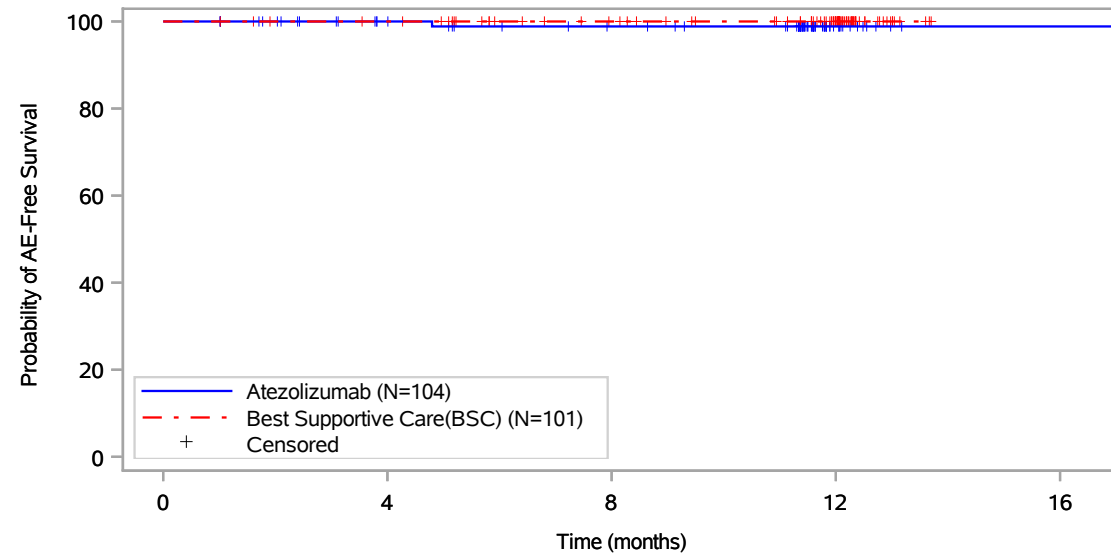
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Palpitations



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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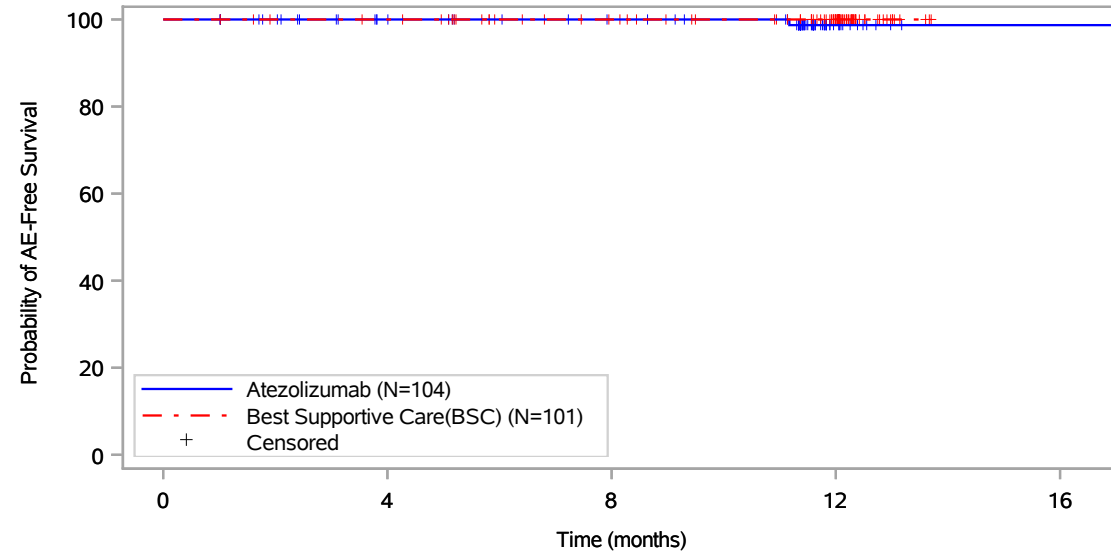
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Cardiac disorders, Sinus bradycardia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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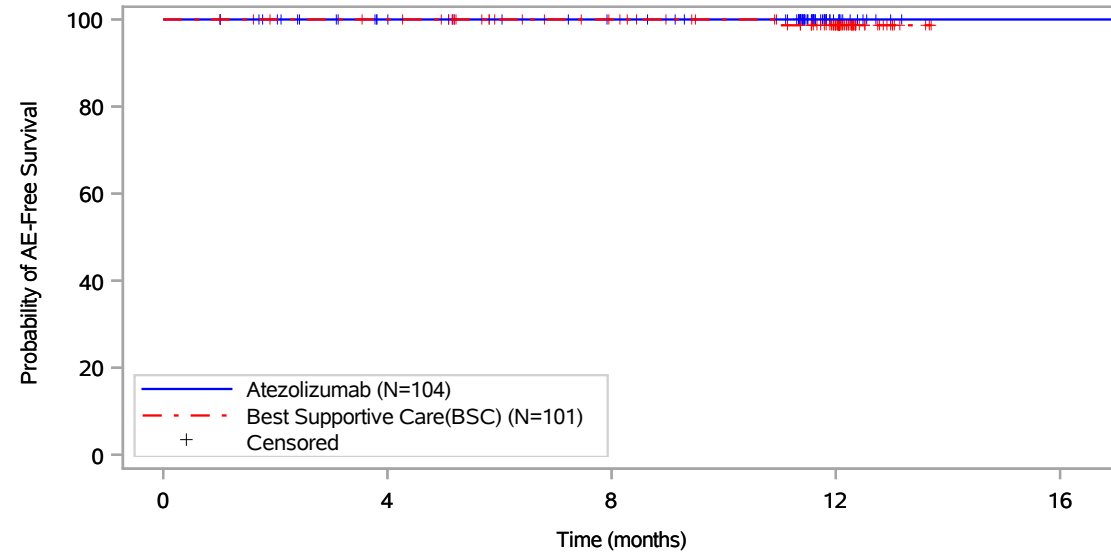
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Congenital, familial and genetic disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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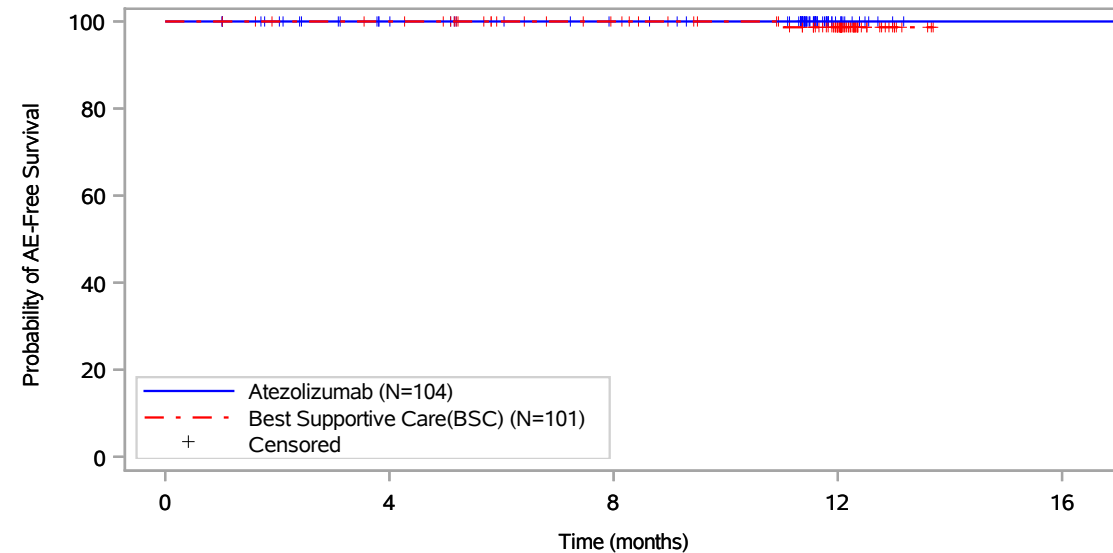
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Congenital, familial and genetic disorders, Gilbert's syndrome



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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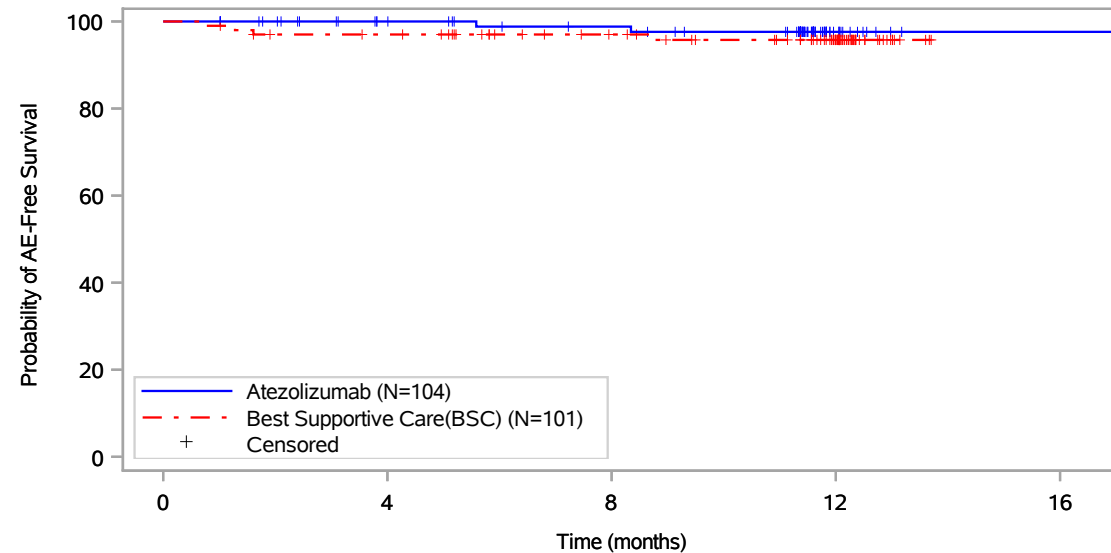
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Ear and labyrinth disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	94	80	52	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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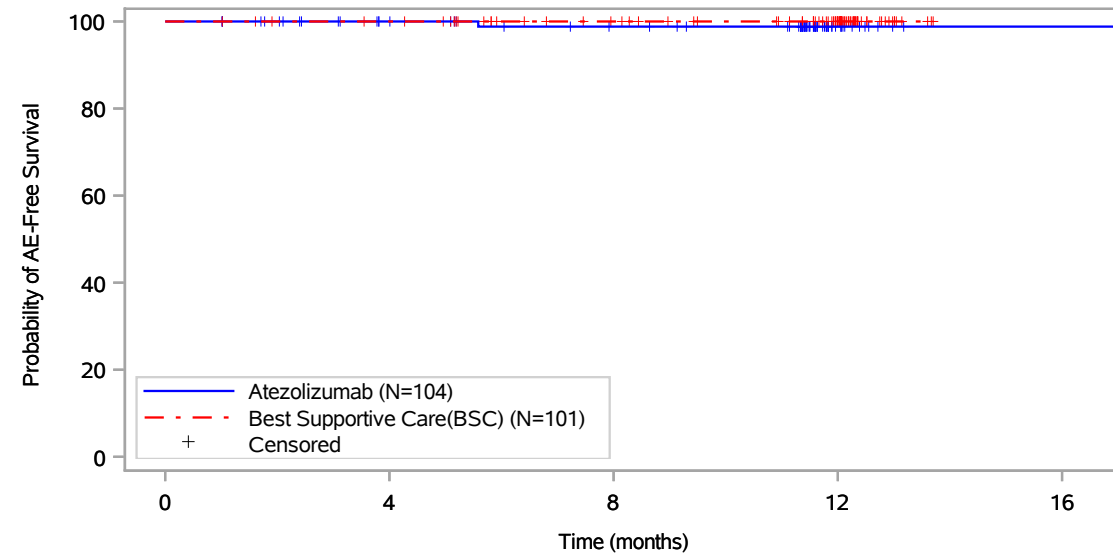
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Ear and labyrinth disorders, Ear discomfort



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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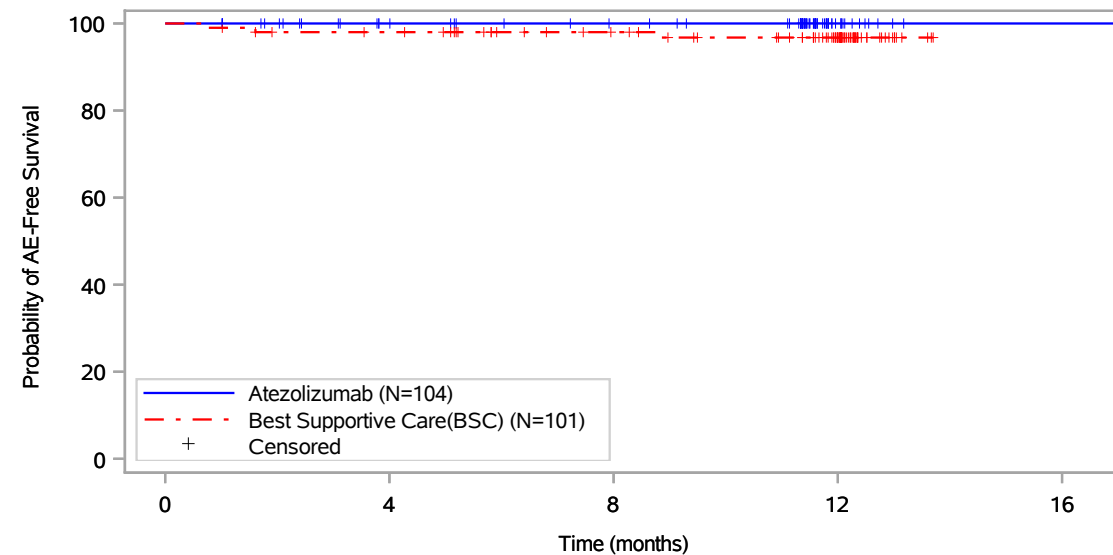
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Ear and labyrinth disorders, Tinnitus



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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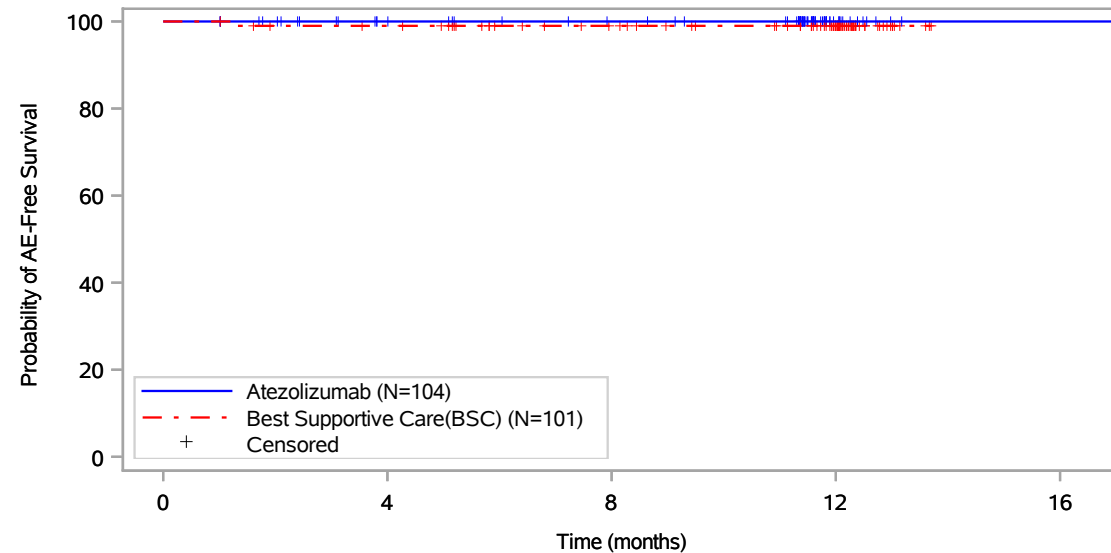
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Ear and labyrinth disorders, Vertigo



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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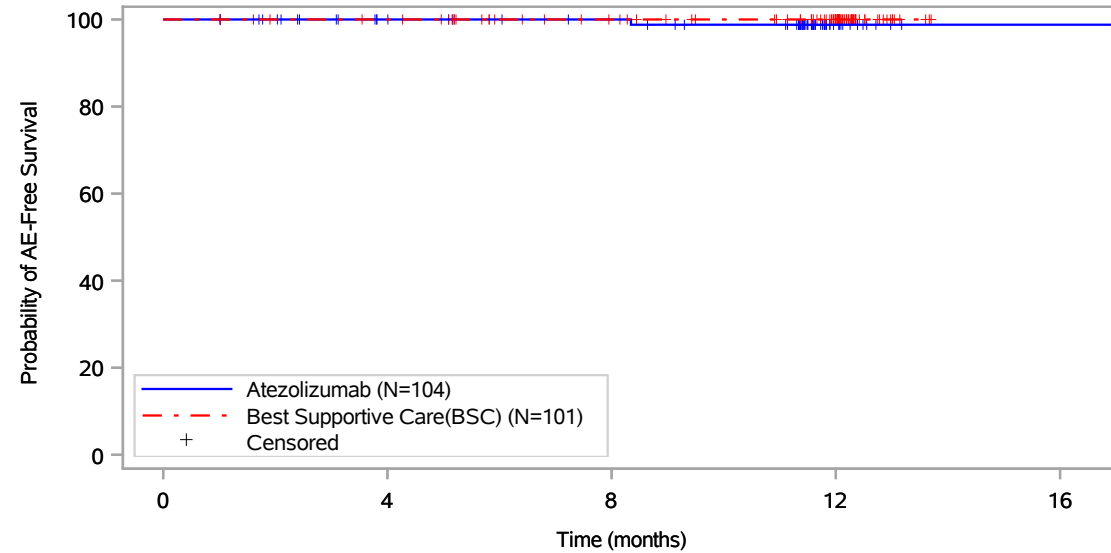
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Ear and labyrinth disorders, Vestibular ataxia



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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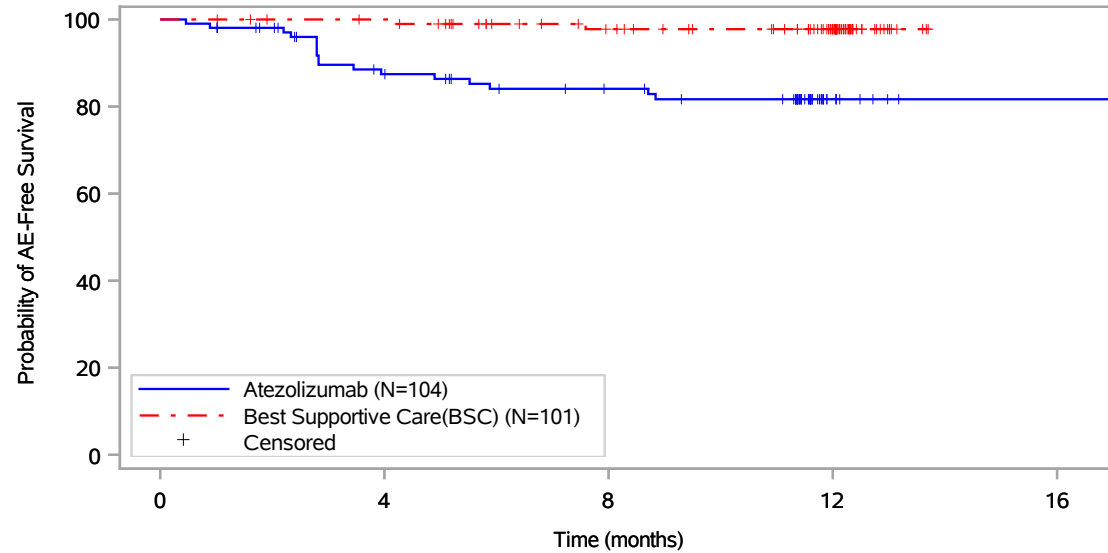
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Endocrine disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	81	71	9	1
Best Supportive Care(BSC) (N=101)	101	97	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	11	18	78	86
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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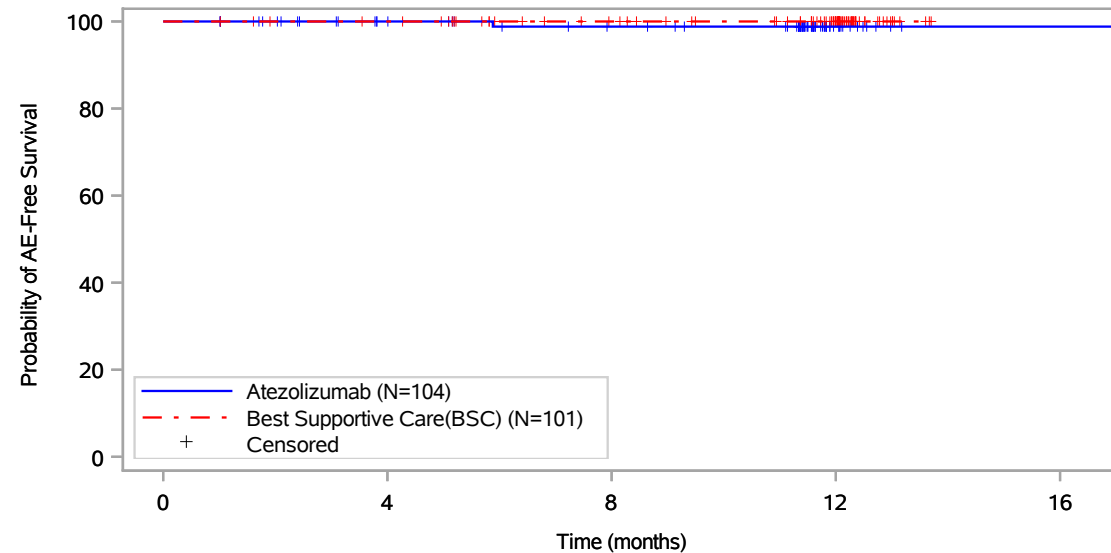
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Endocrine disorders, Autoimmune thyroiditis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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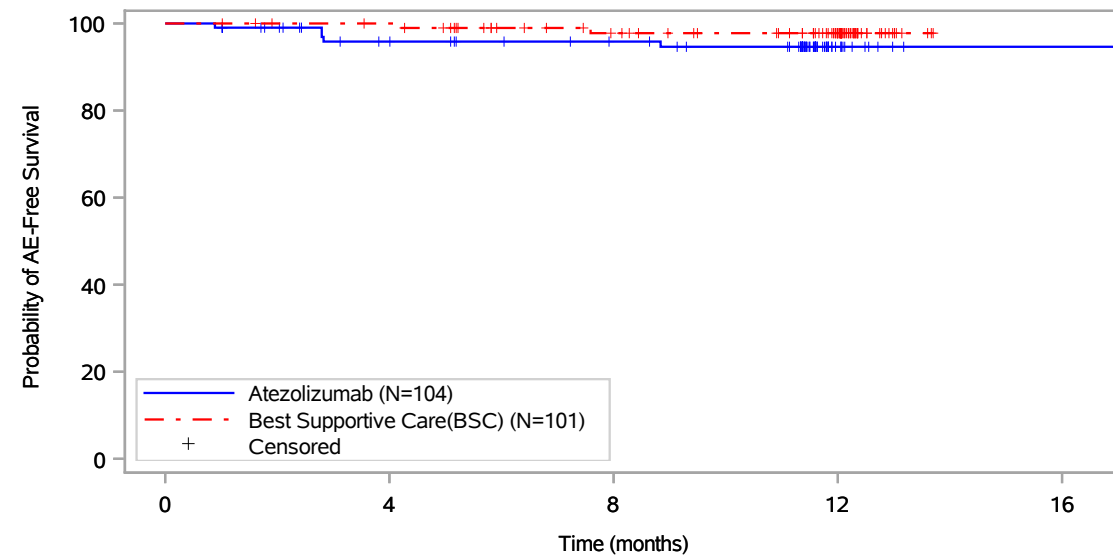
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Endocrine disorders, Hyperthyroidism



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	12	19	87	98
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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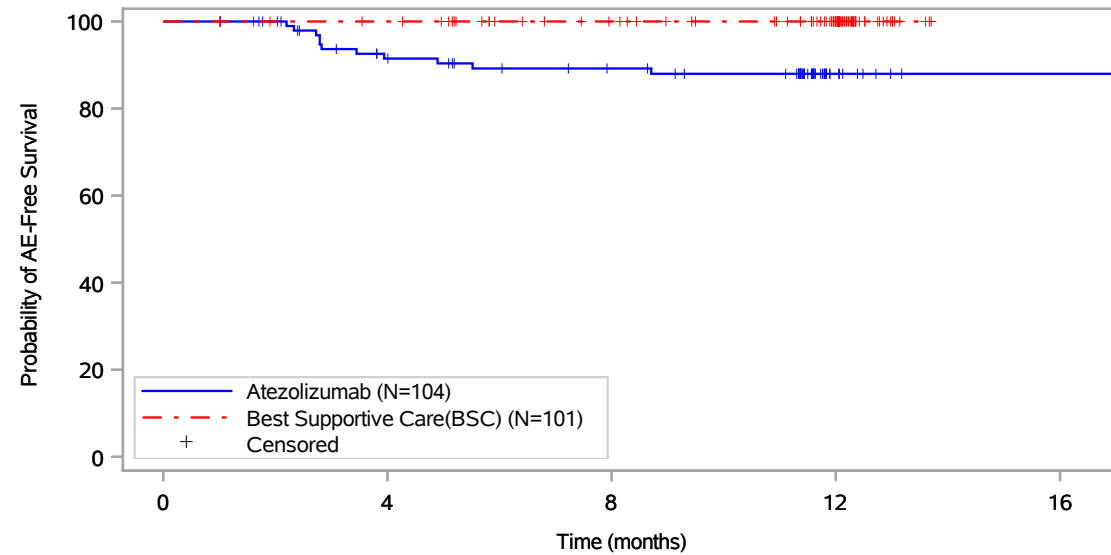
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Endocrine disorders, Hypothyroidism



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	83	74	10	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	83	92
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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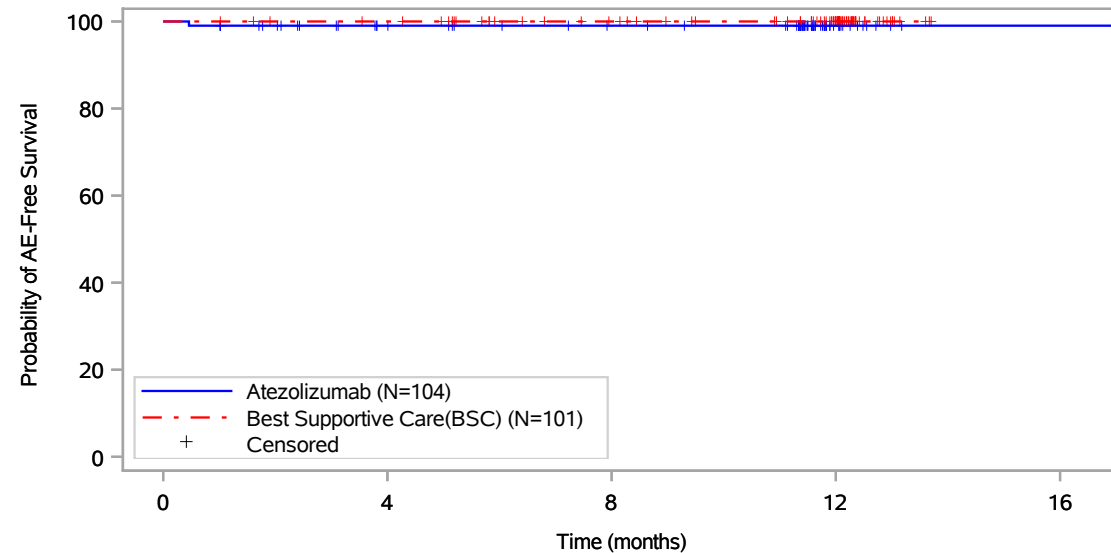
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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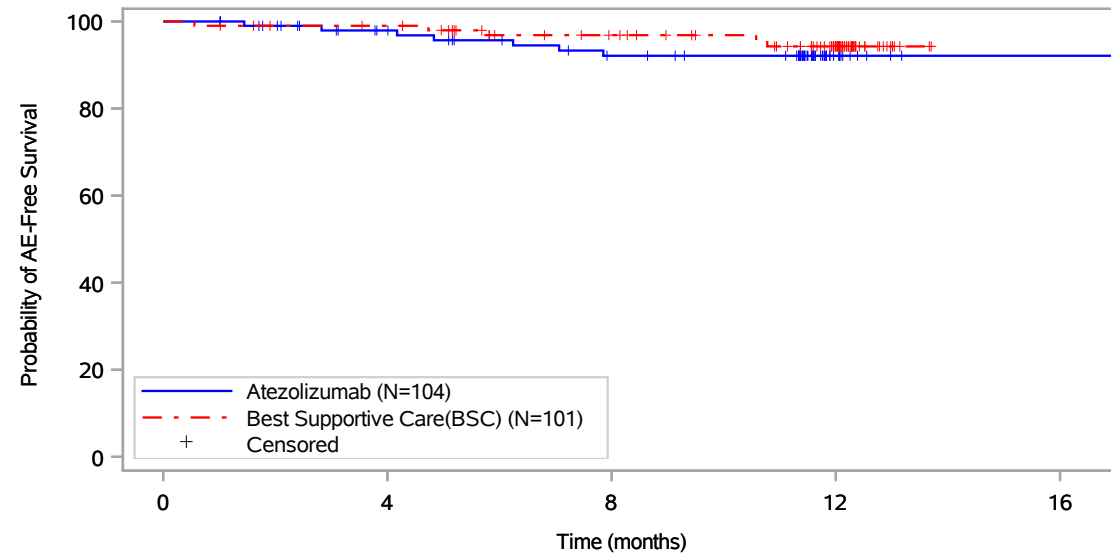
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	76	11	1
Best Supportive Care(BSC) (N=101)	101	96	81	52	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	86	96
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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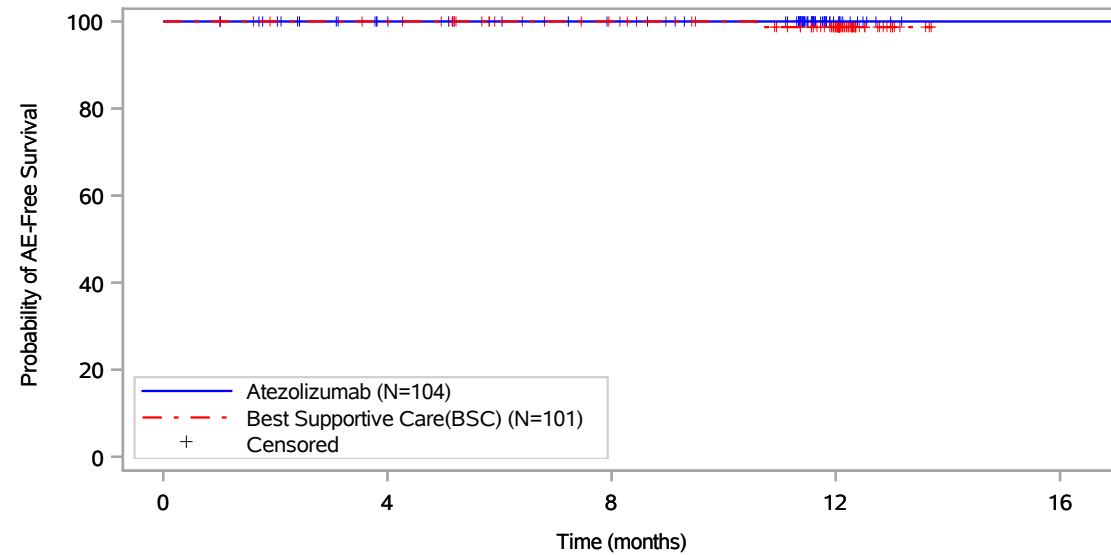
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Blepharitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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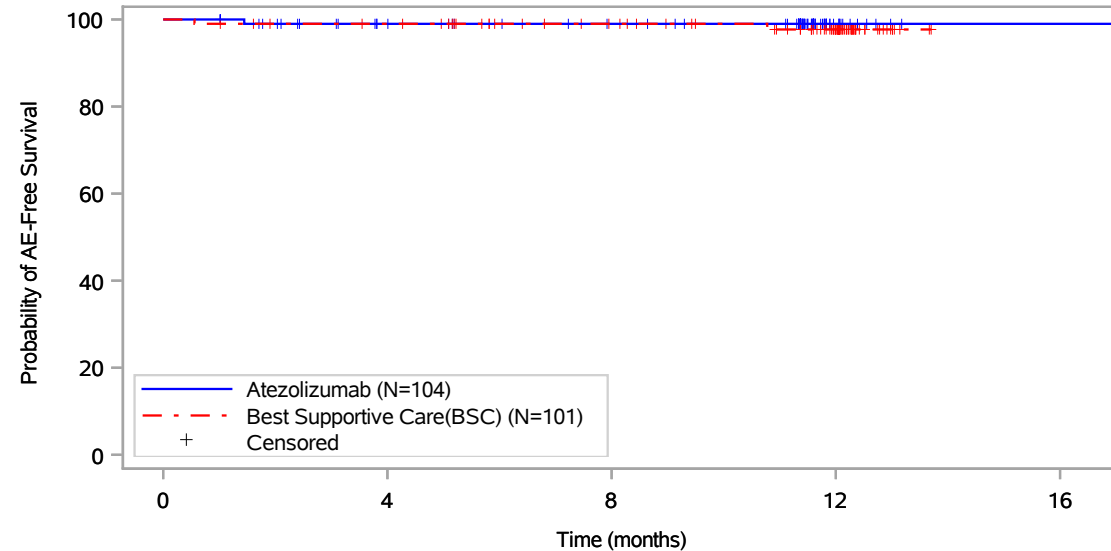
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Cataract



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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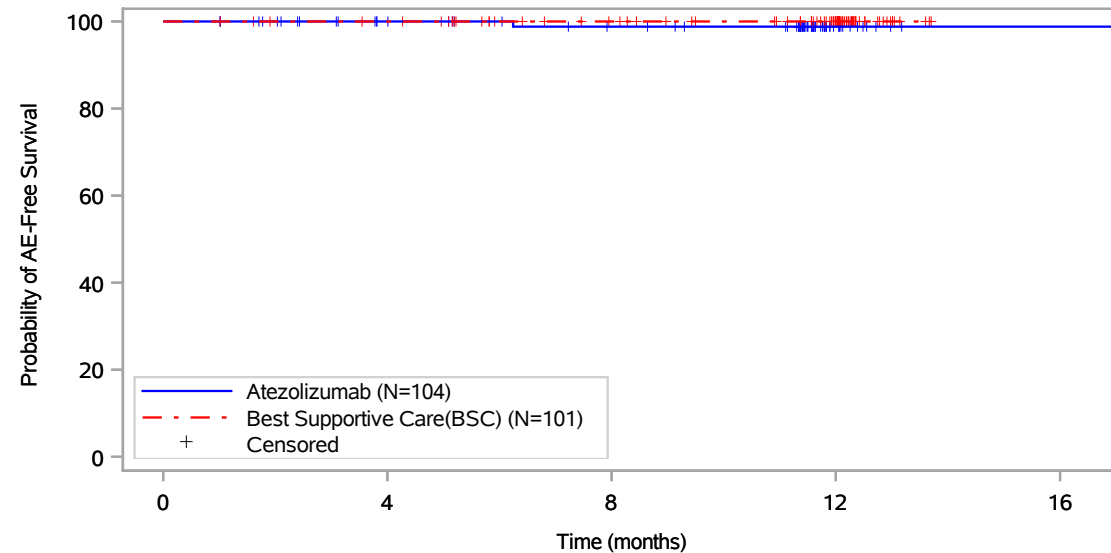
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Dry eye



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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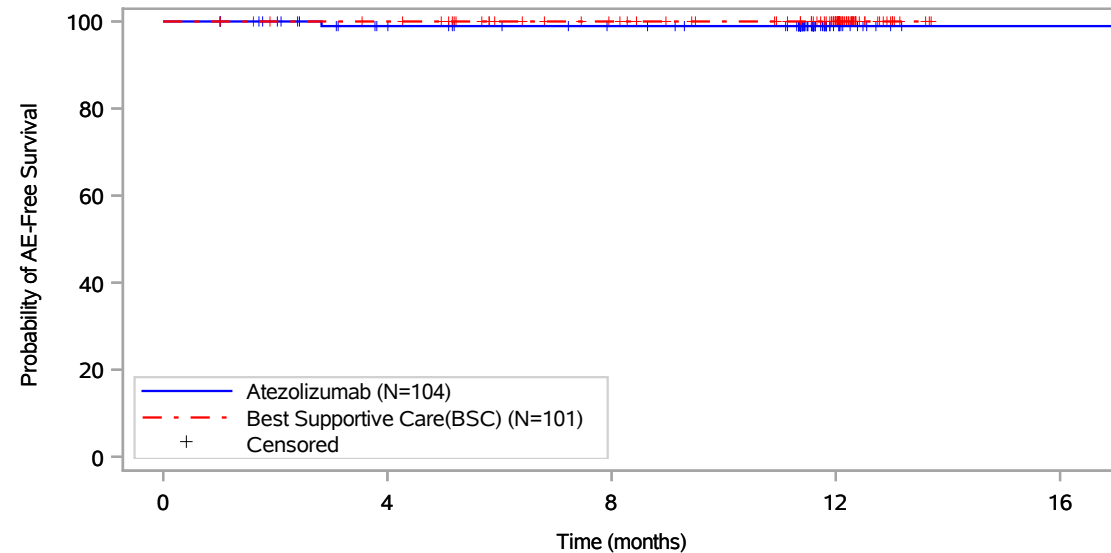
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Eyelid oedema



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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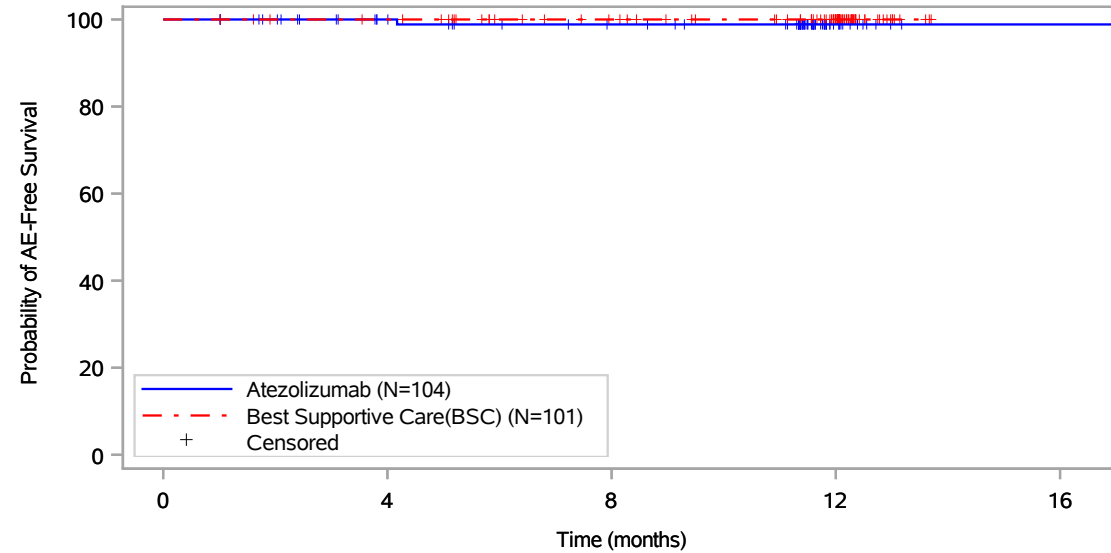
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Ocular discomfort



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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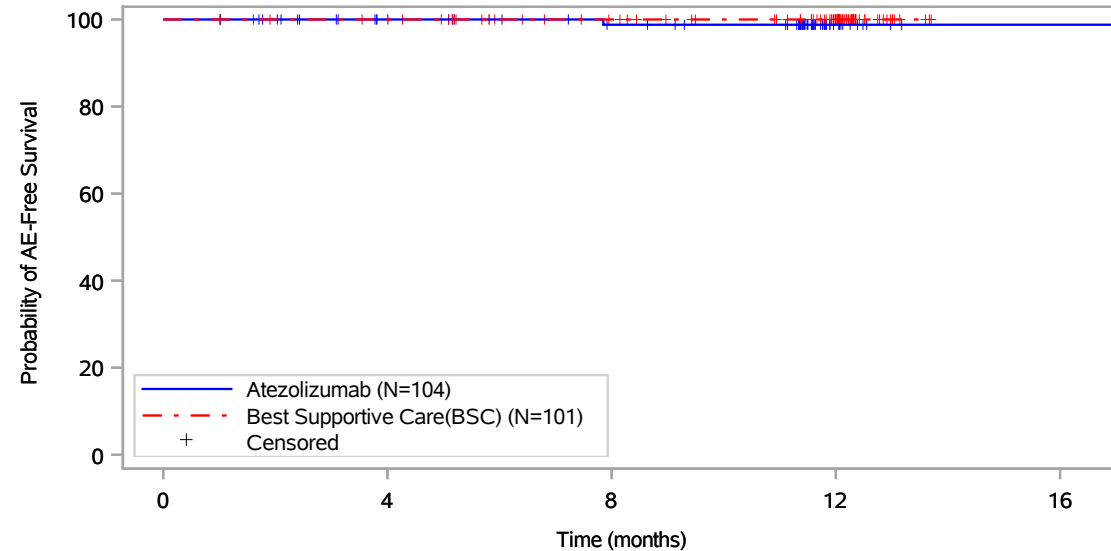
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Retinal detachment



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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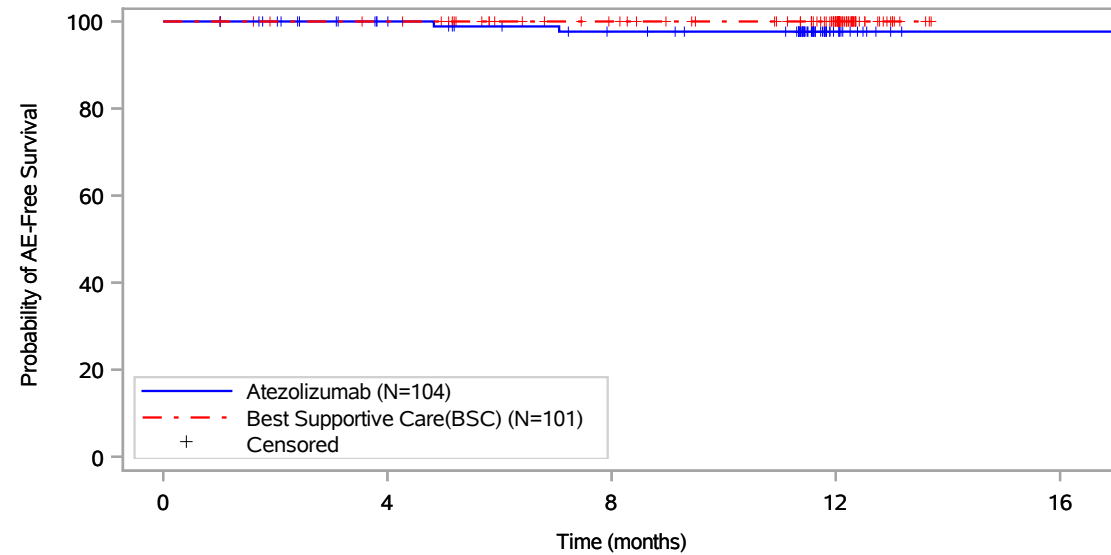
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Vision blurred



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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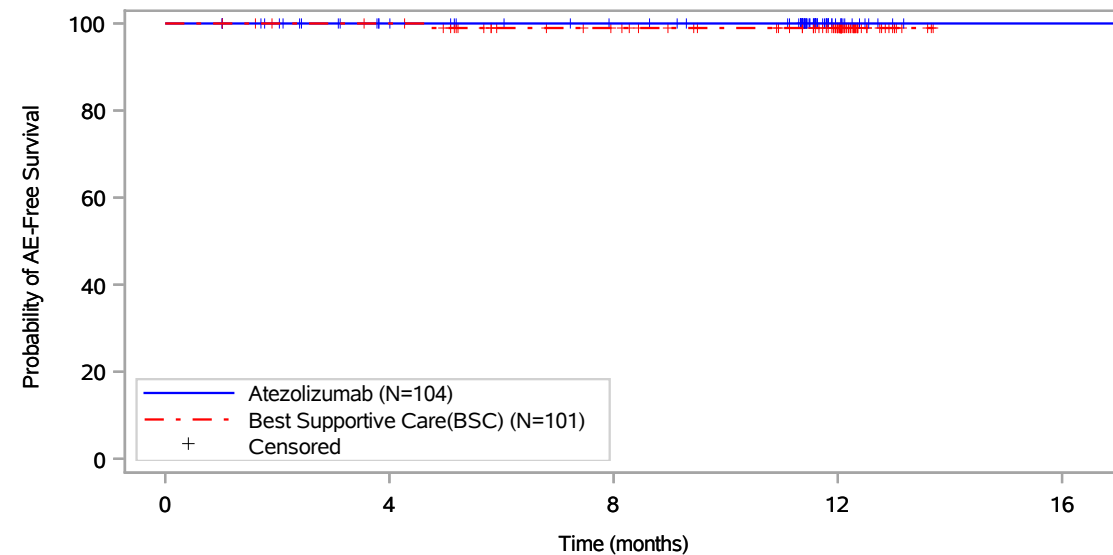
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Visual impairment



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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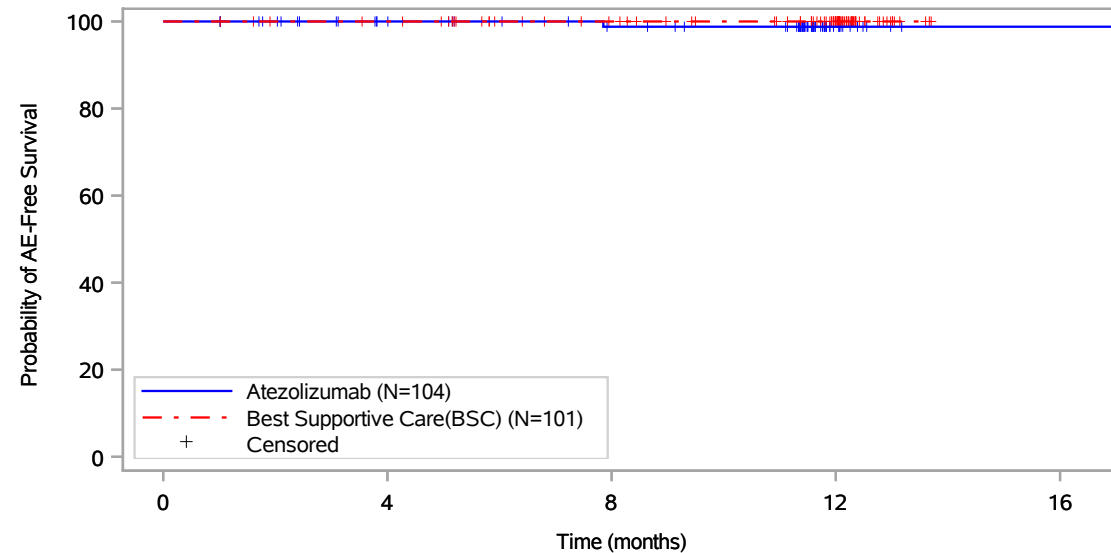
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Vitreous floaters



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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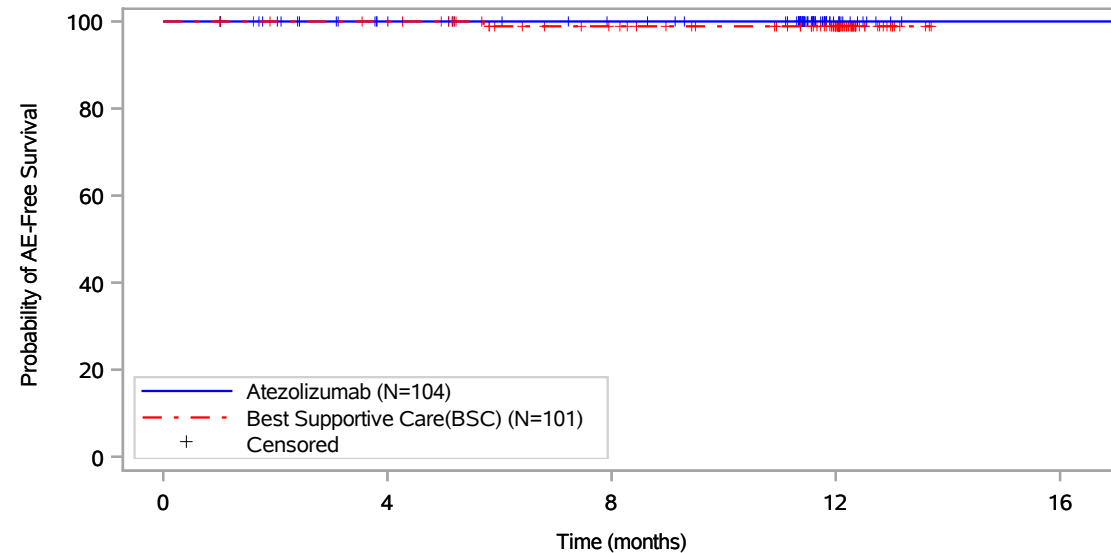
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Eye disorders, Vitreous haemorrhage



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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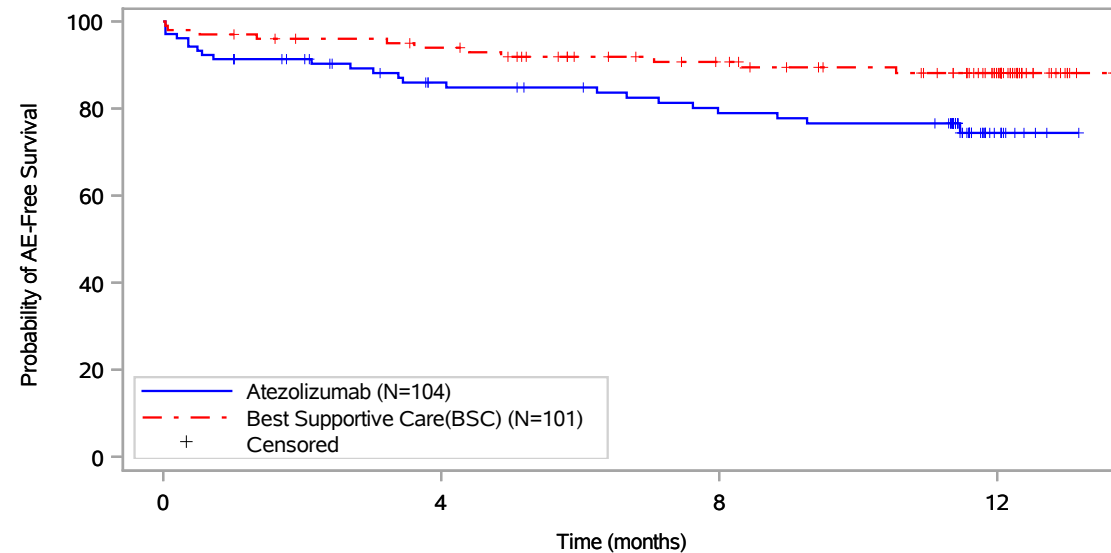
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	76	67	10
Best Supportive Care(BSC) (N=101)	101	91	75	48
Patients censored				
Atezolizumab (N=104)	0	14	17	71
Best Supportive Care(BSC) (N=101)	0	4	17	42

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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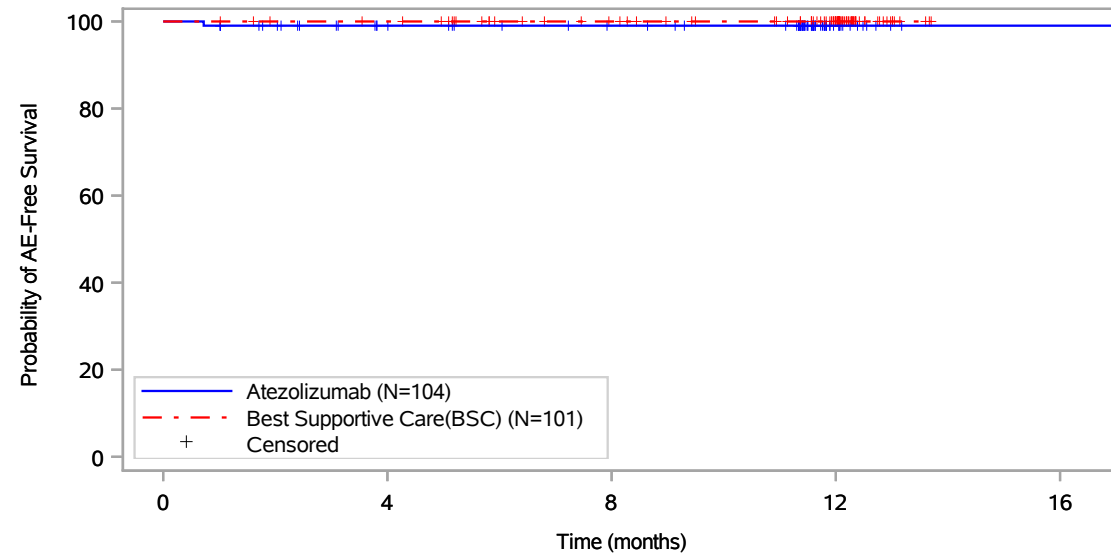
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal distension



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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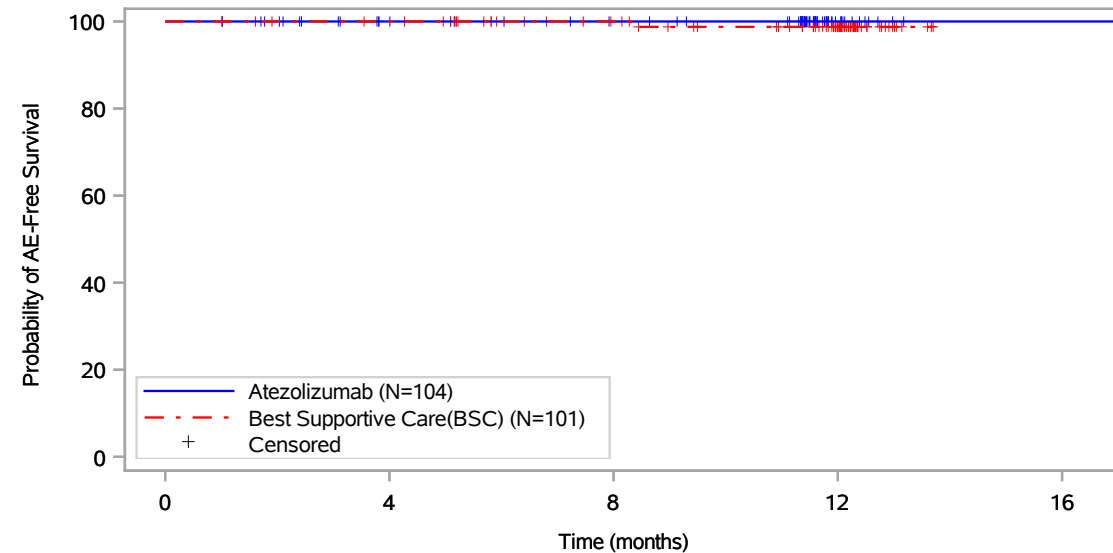
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal hernia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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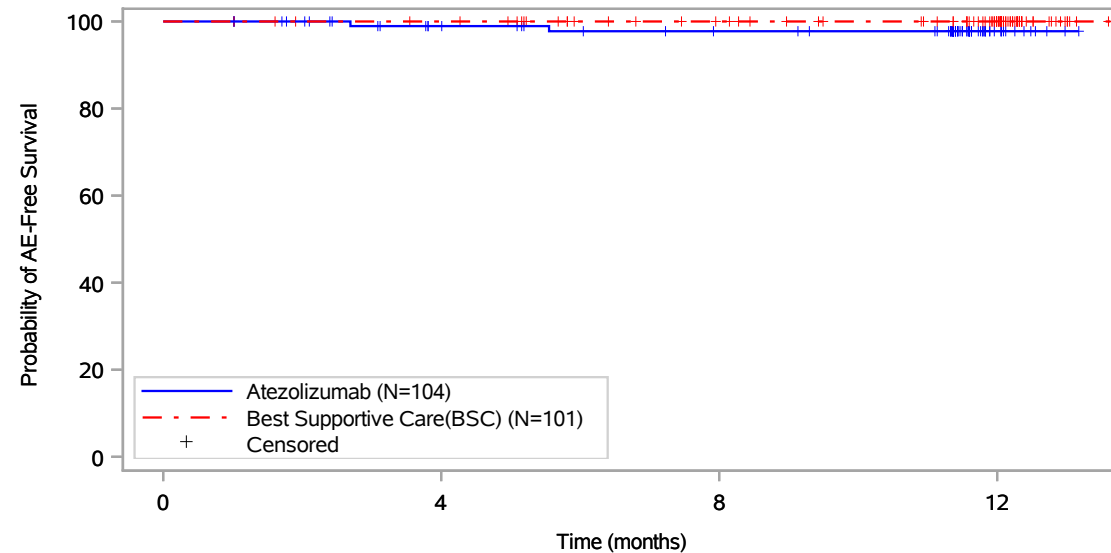
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal pain



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	88	80	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	15	22	90
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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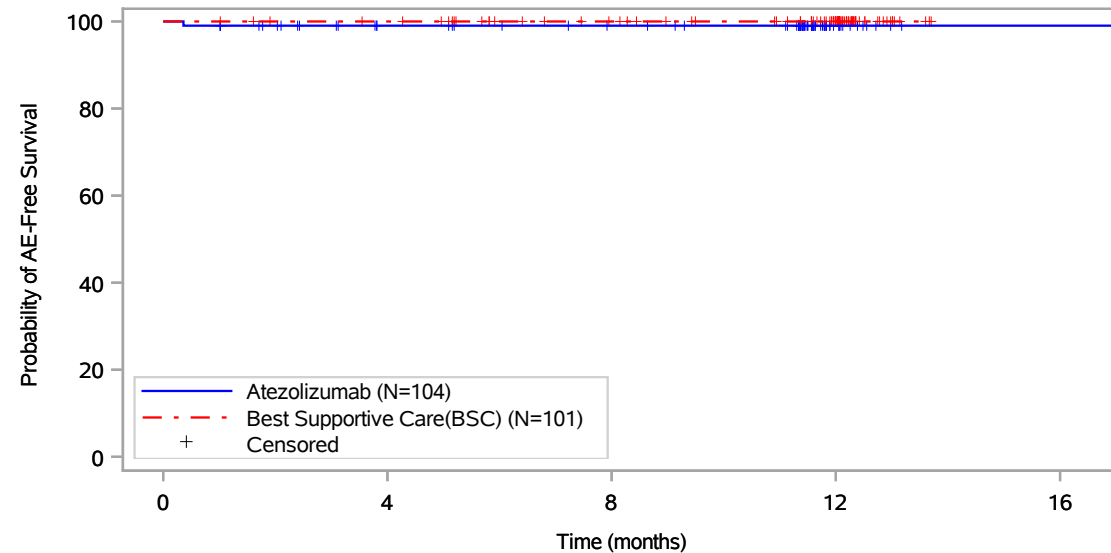
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal pain lower



Patients at risk					
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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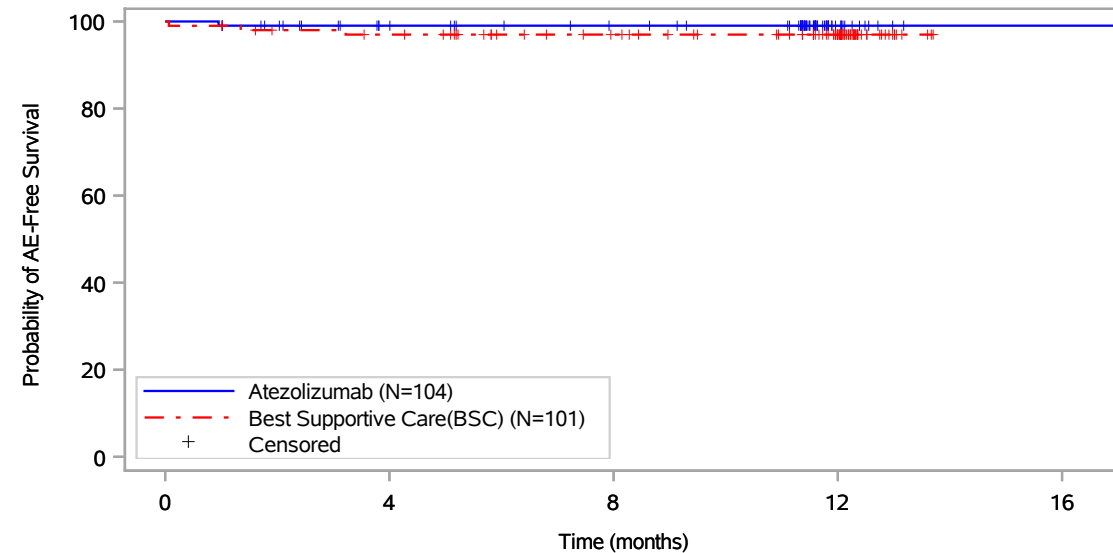
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal pain upper



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	94	80	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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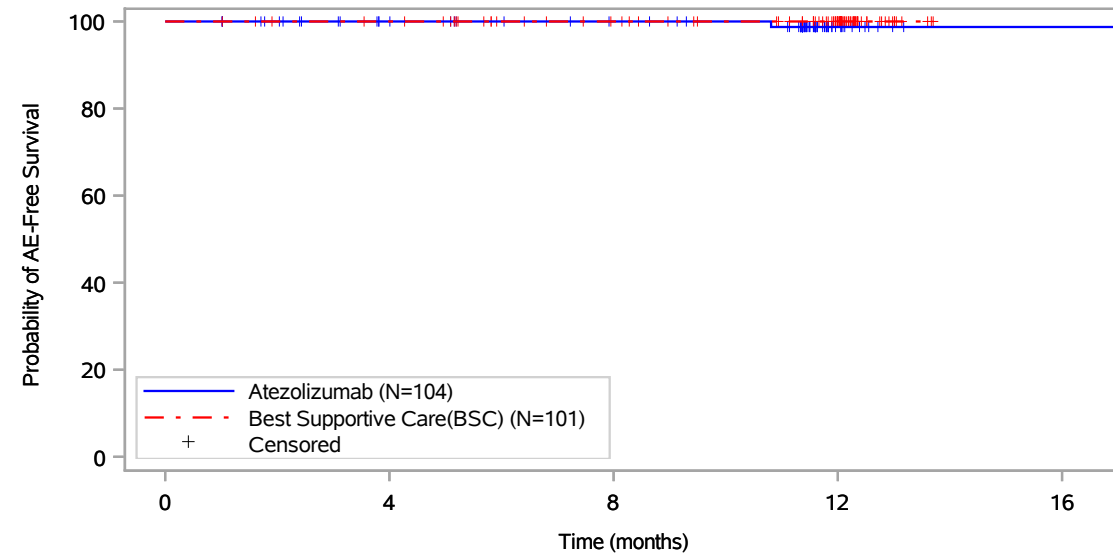
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Bowel movement irregularity



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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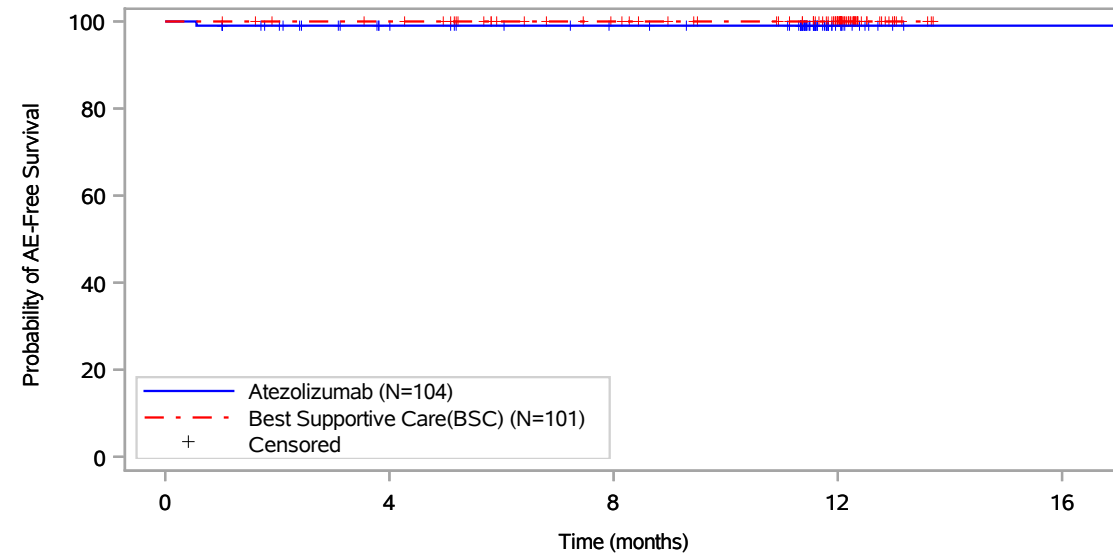
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Cheilitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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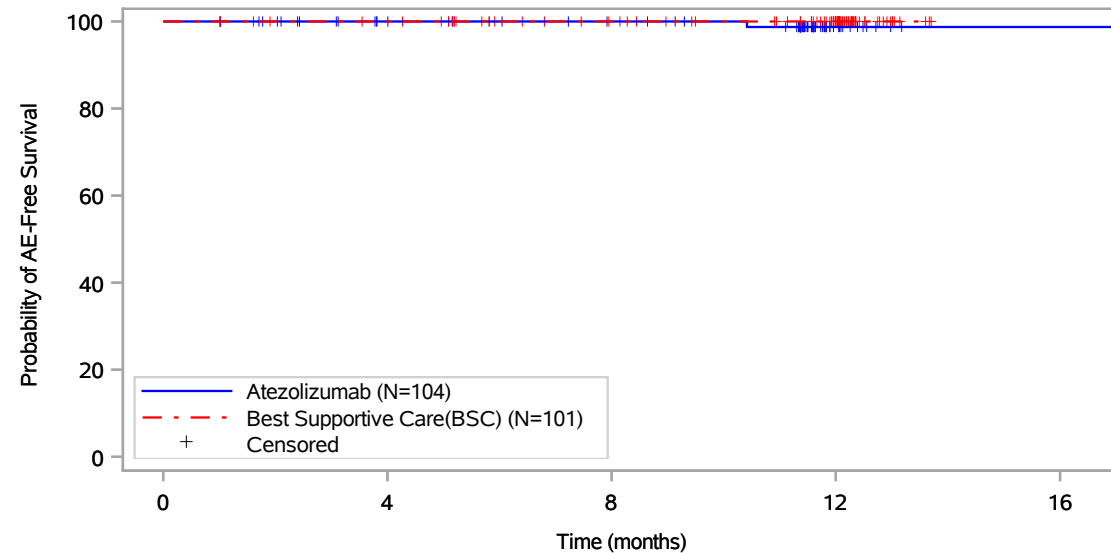
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Colitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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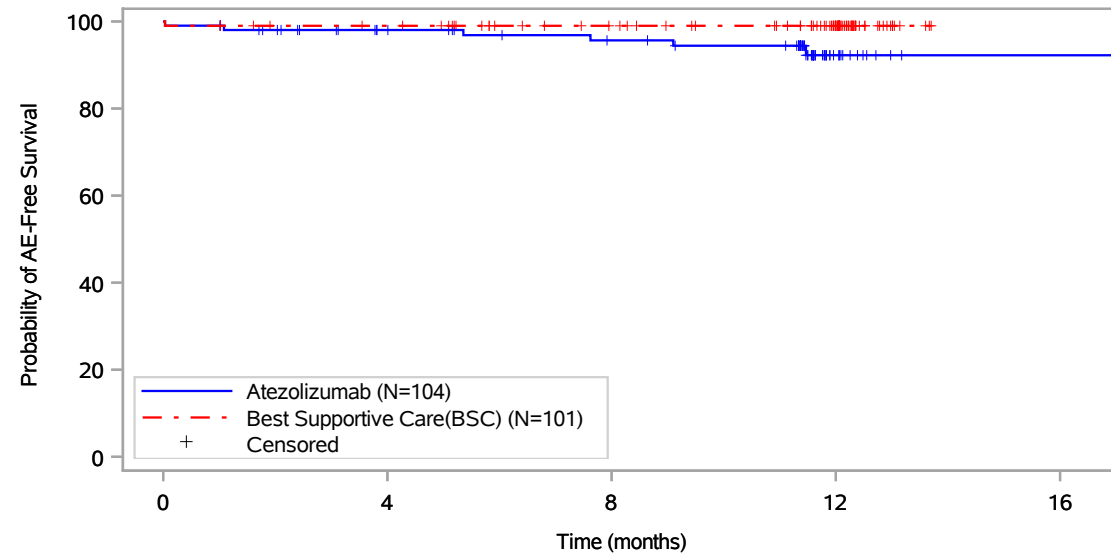
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Constipation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	85	97
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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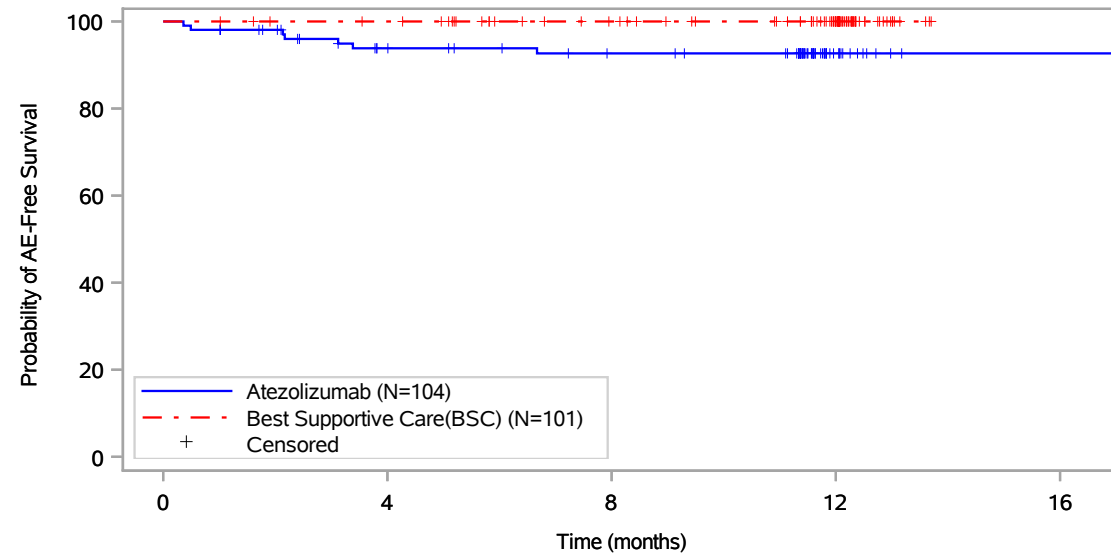
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Diarrhoea



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	84	77	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	84	96
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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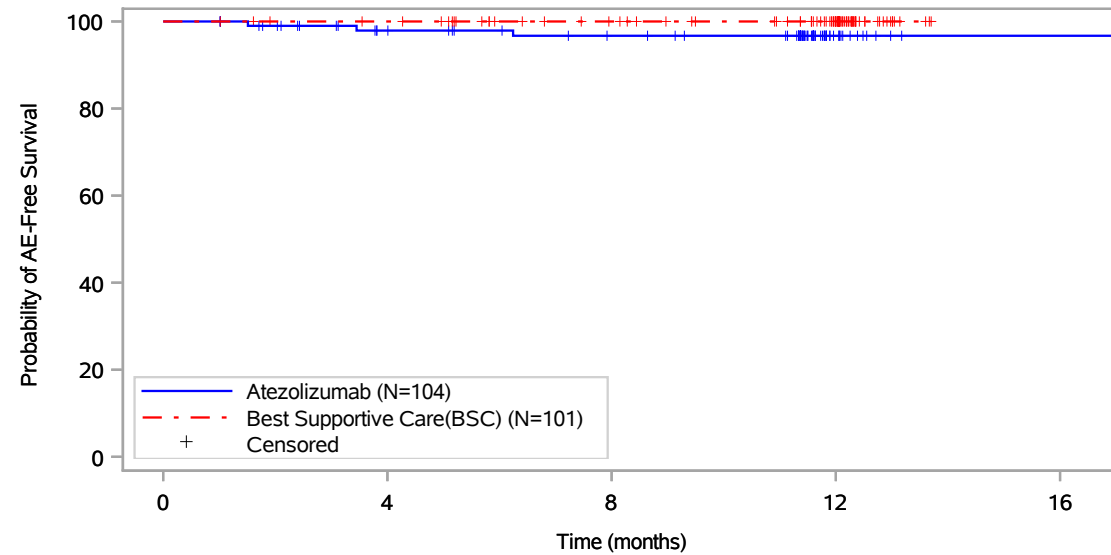
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Dry mouth



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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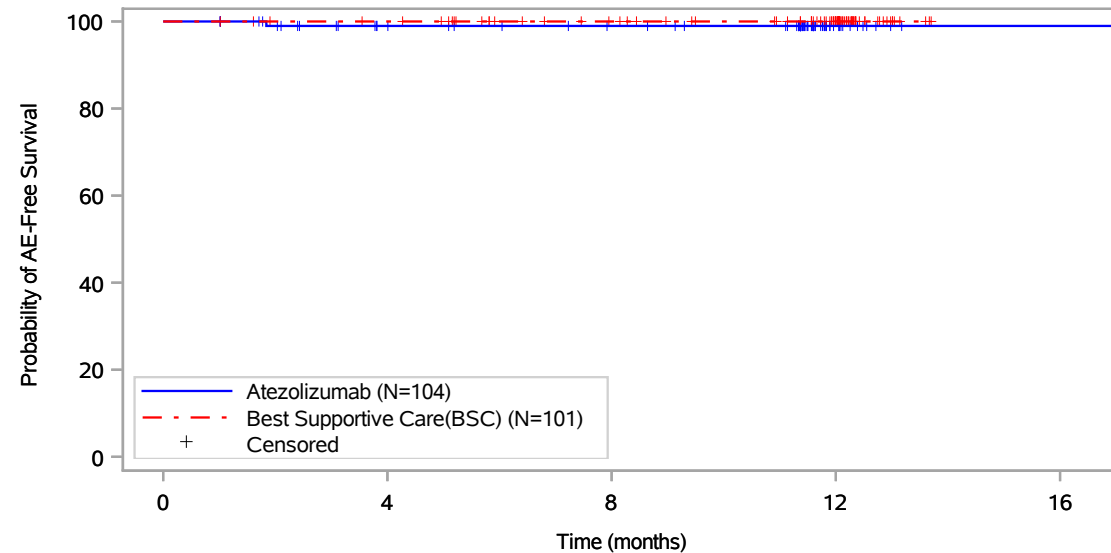
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Dyspepsia



Patients at risk					
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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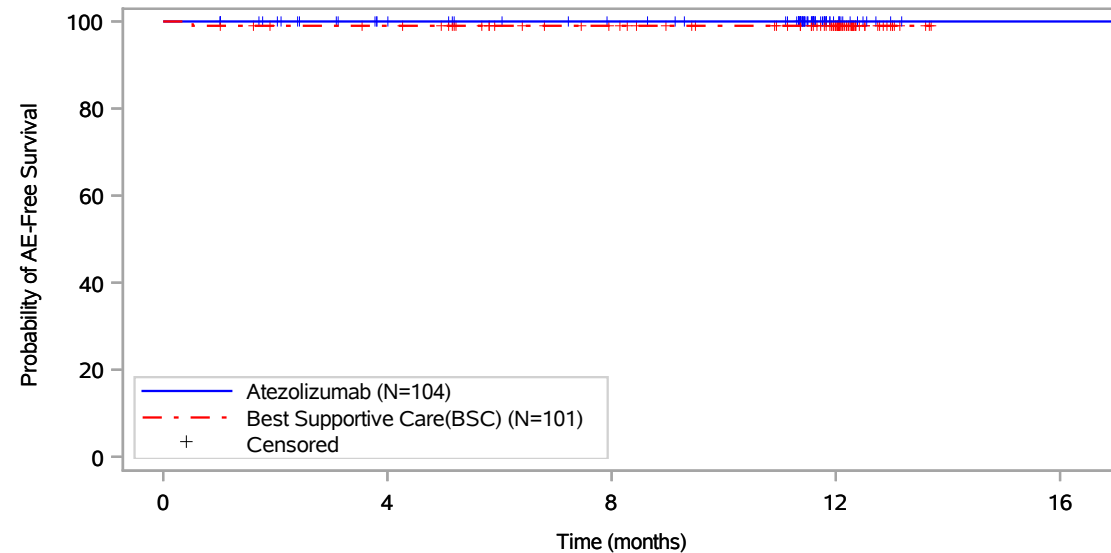
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Dysphagia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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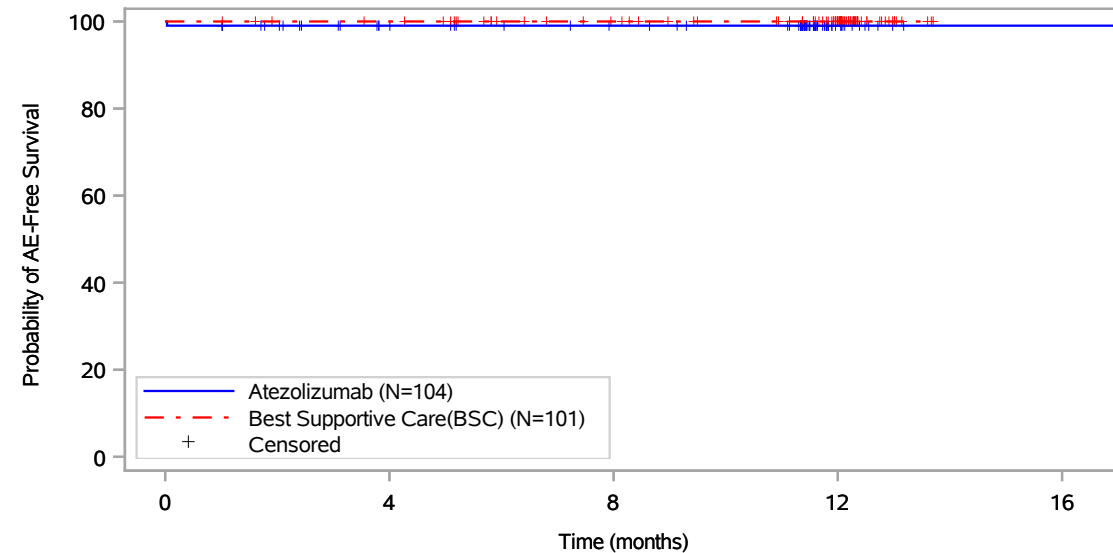
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Faeces soft



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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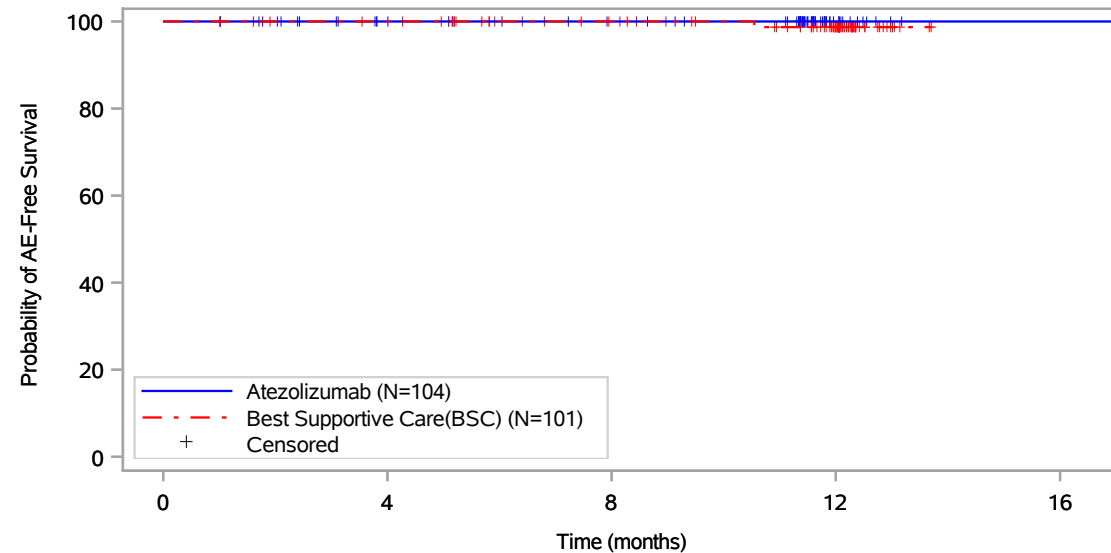
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Flatulence



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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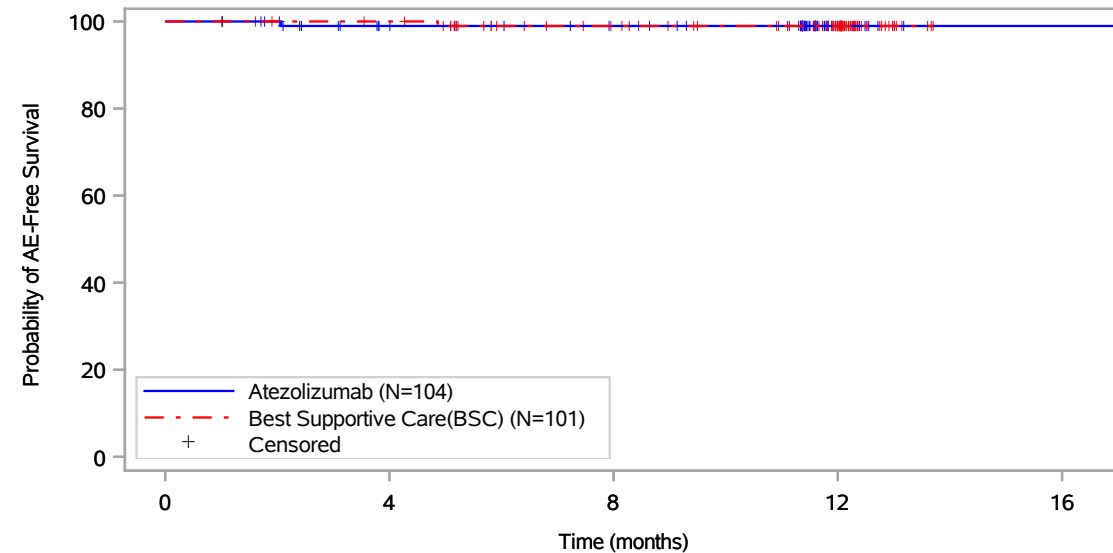
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Gastrooesophageal reflux disease



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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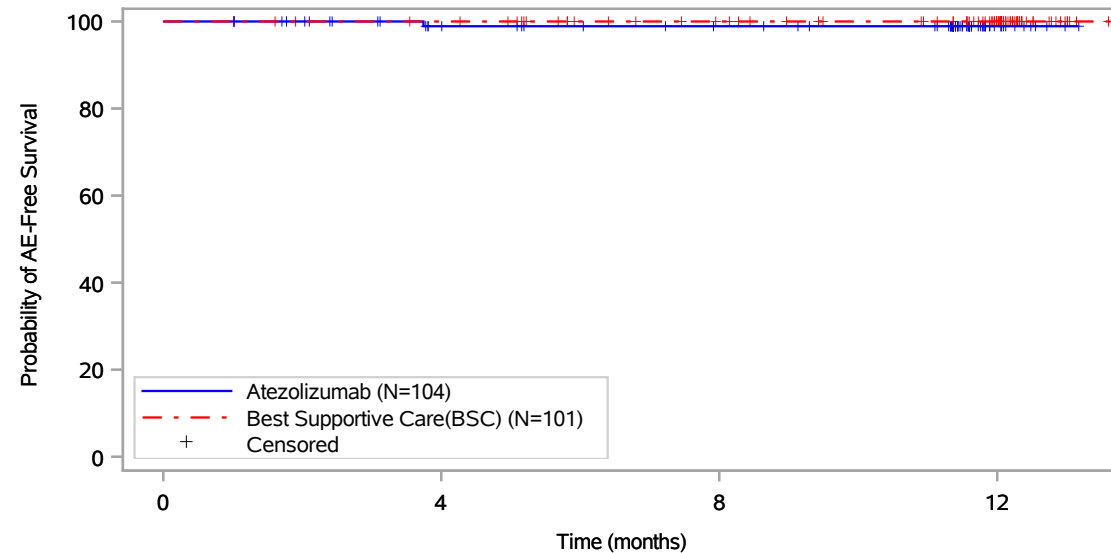
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Haemorrhoids



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	88	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	15	22	91
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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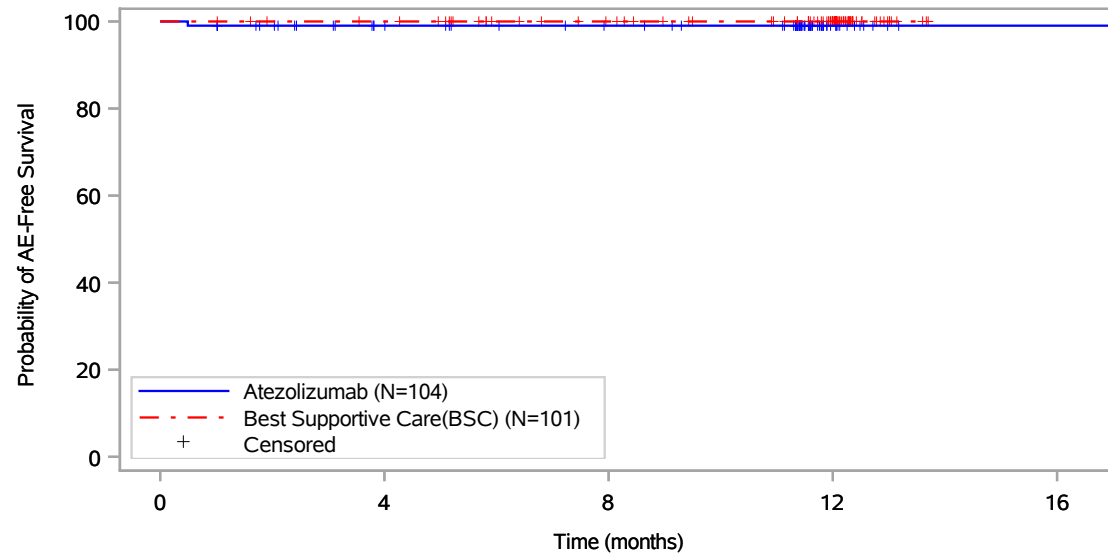
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Hyperaesthesia teeth



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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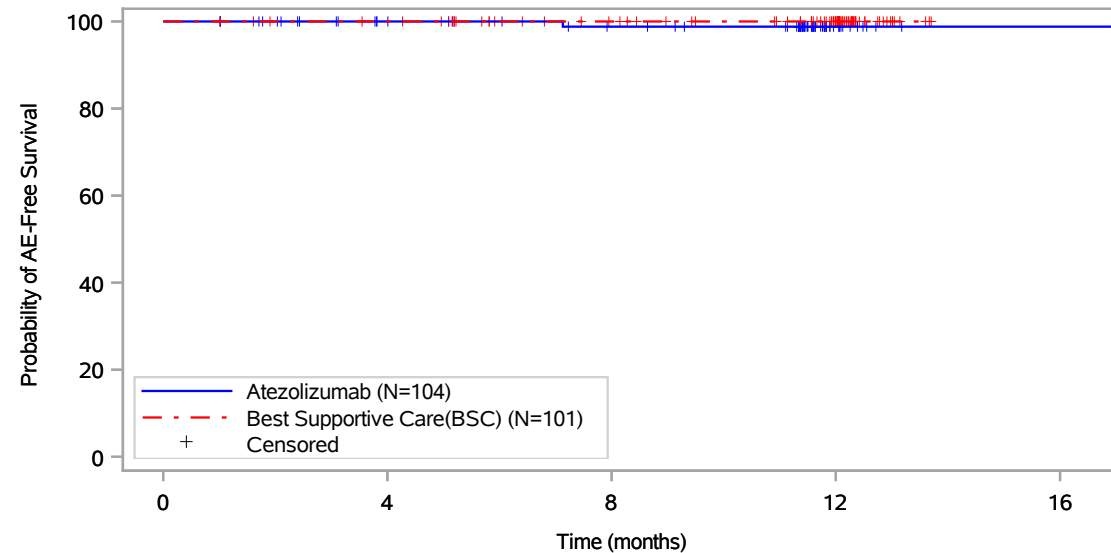
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Large intestine polyp



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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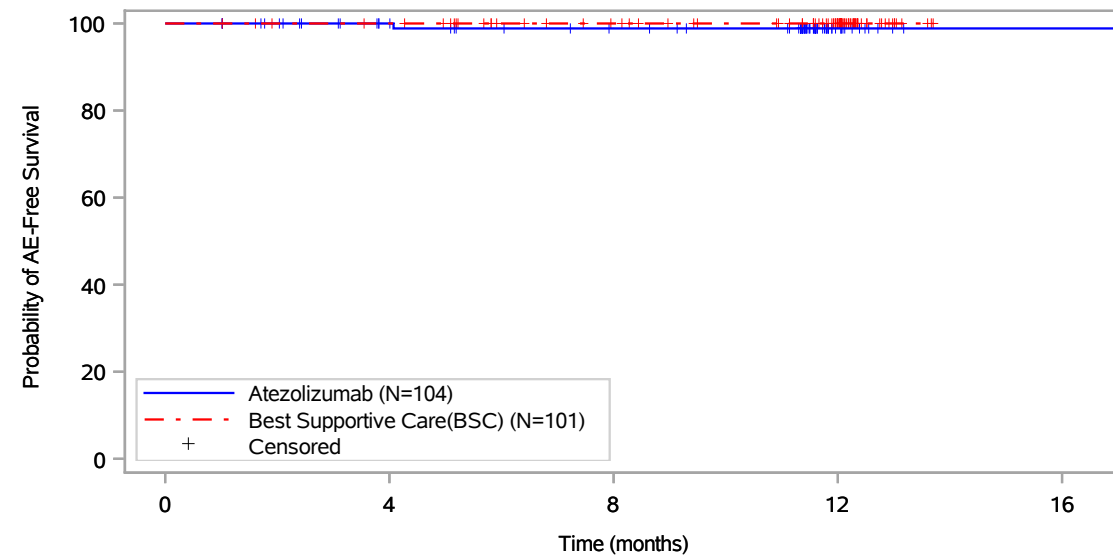
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Mouth ulceration



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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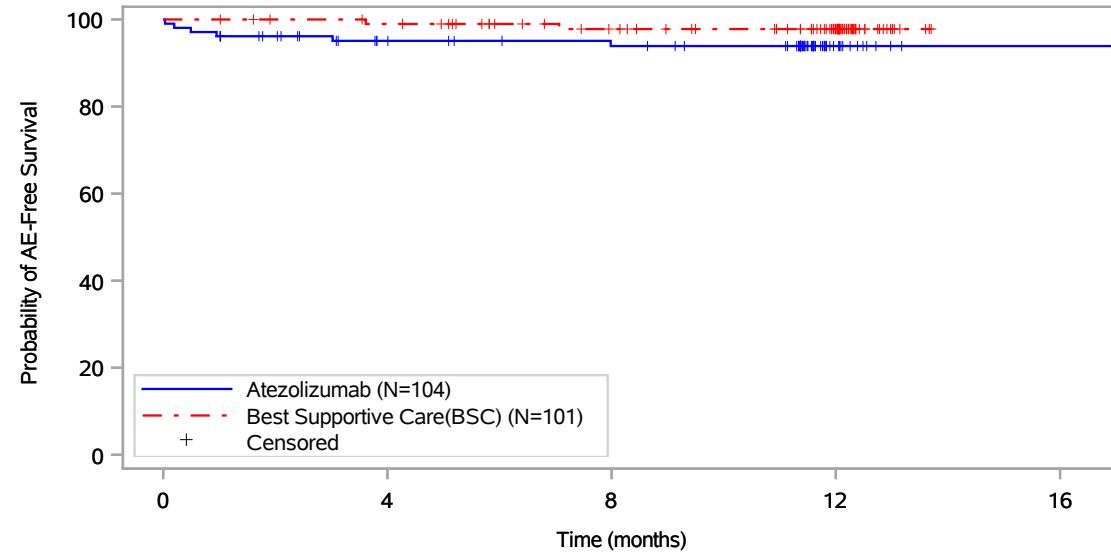
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Nausea



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	84	79	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	19	85	97
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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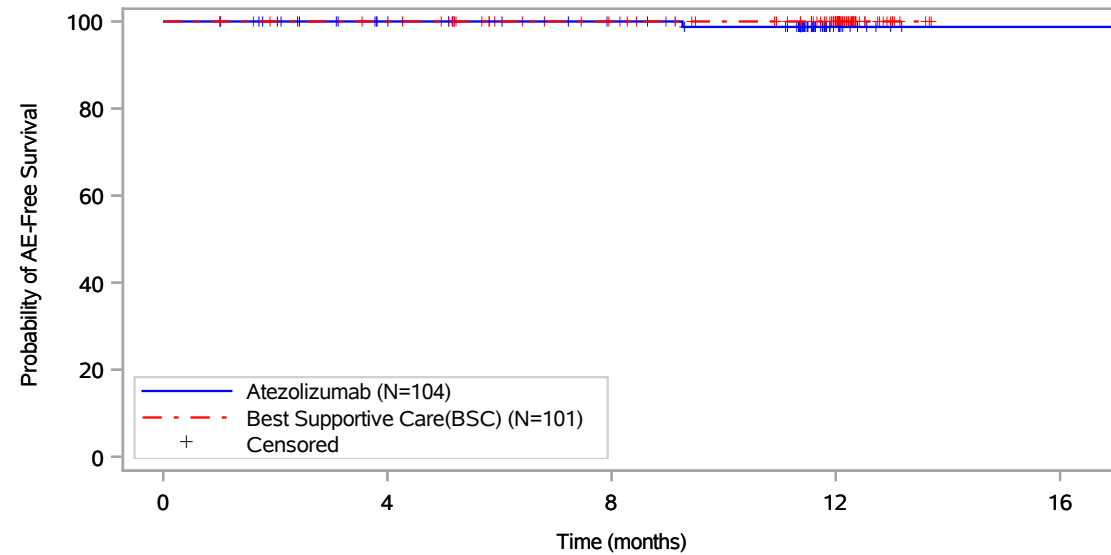
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Stomatitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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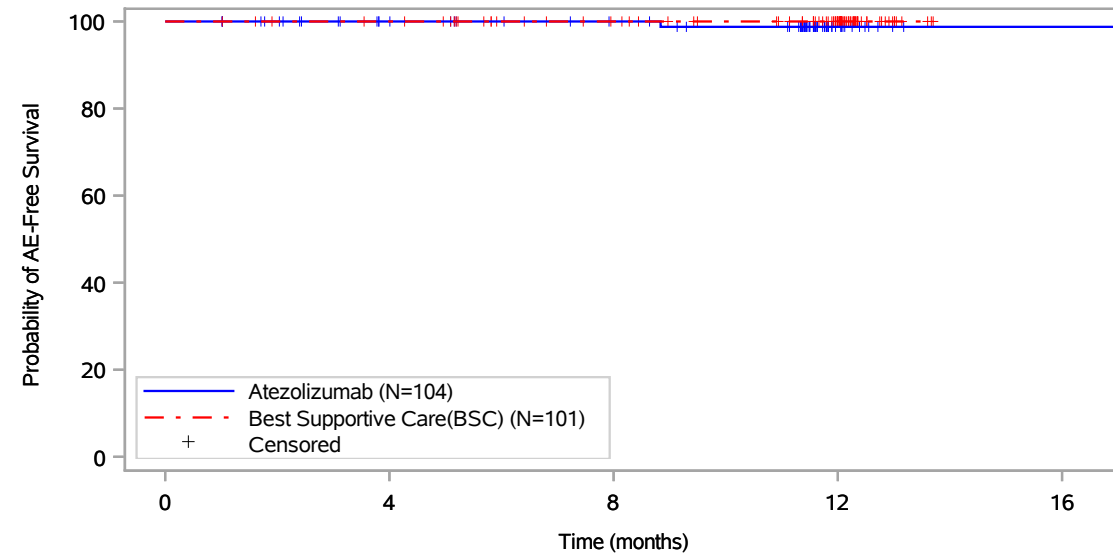
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Toothache



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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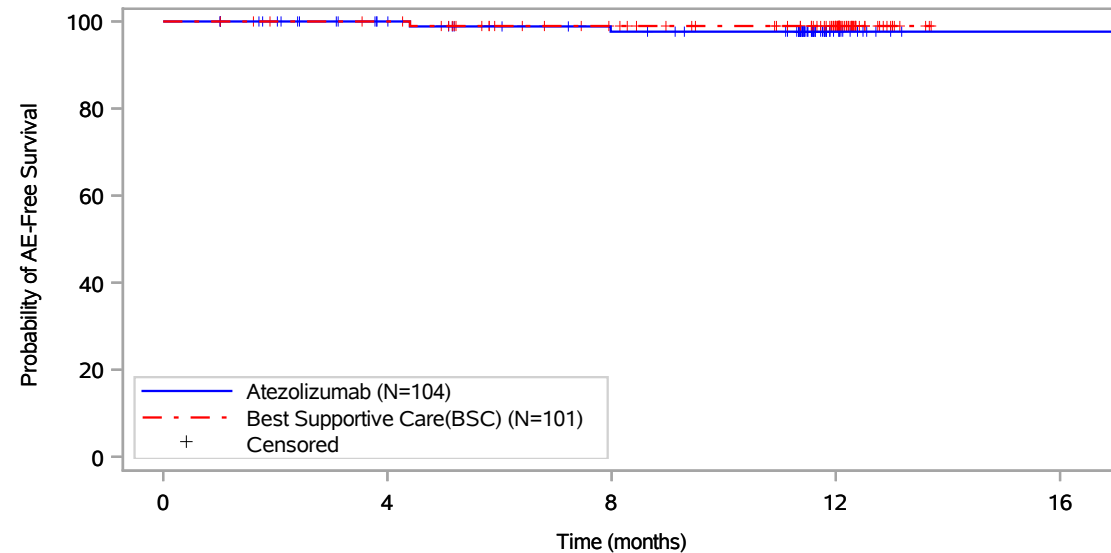
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Vomiting



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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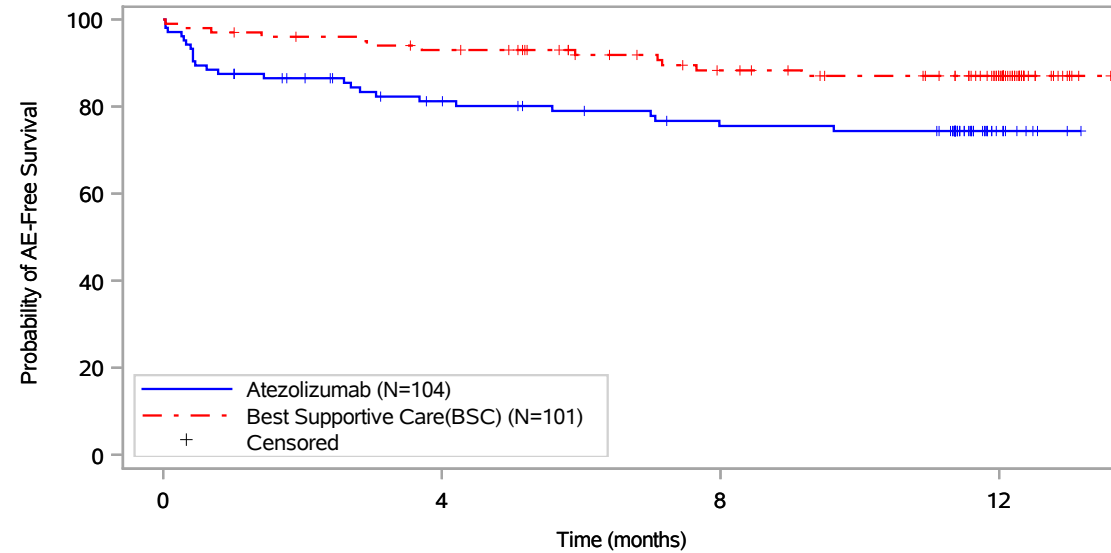
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	75	65	10
Best Supportive Care(BSC) (N=101)	101	91	73	47
Patients censored				
Atezolizumab (N=104)	0	10	15	69
Best Supportive Care(BSC) (N=101)	0	3	17	42

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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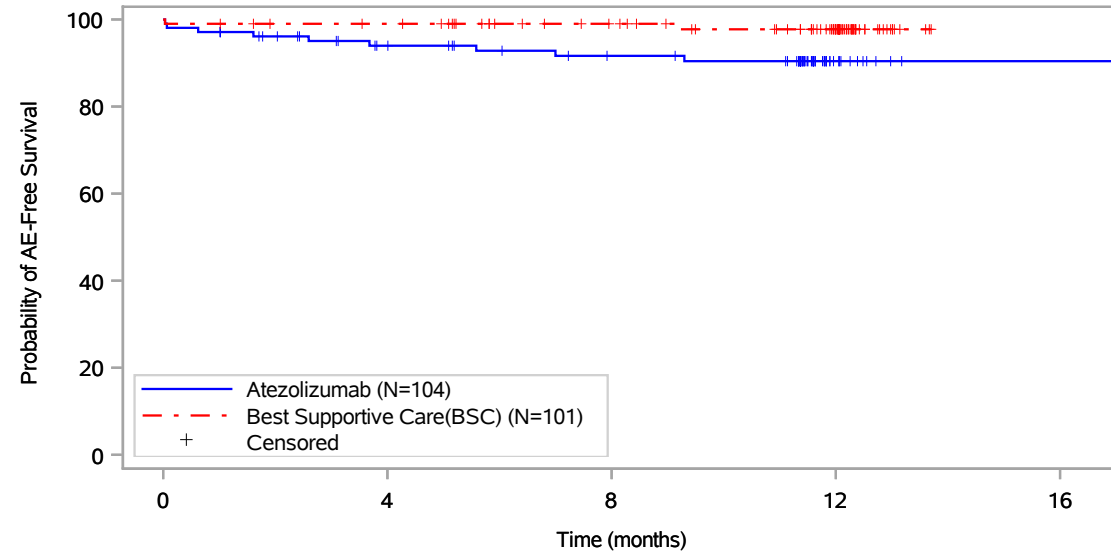
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Asthenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	85	76	12	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	83	94
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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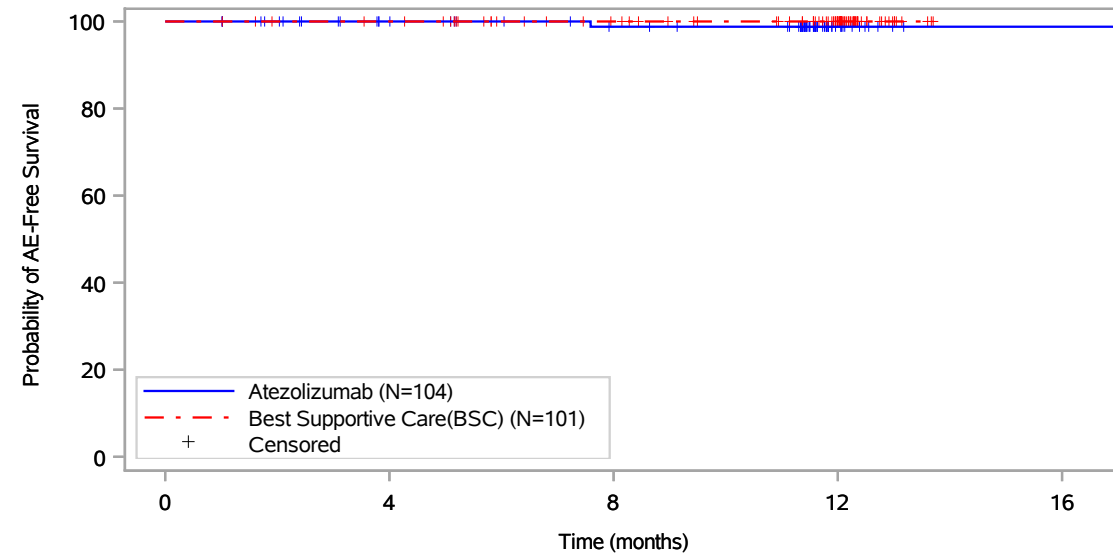
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Catheter site haematoma



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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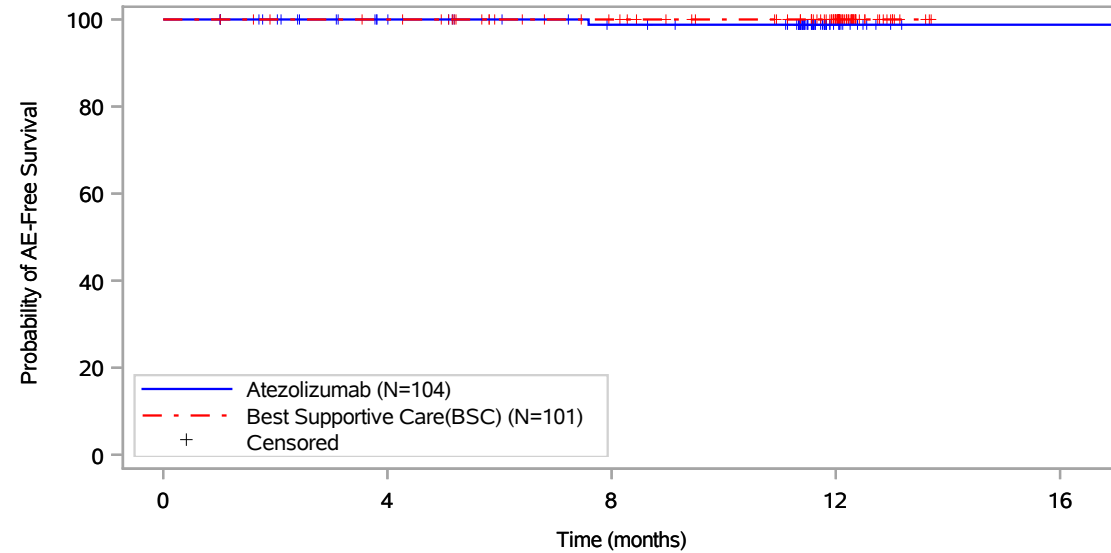
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Catheter site pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

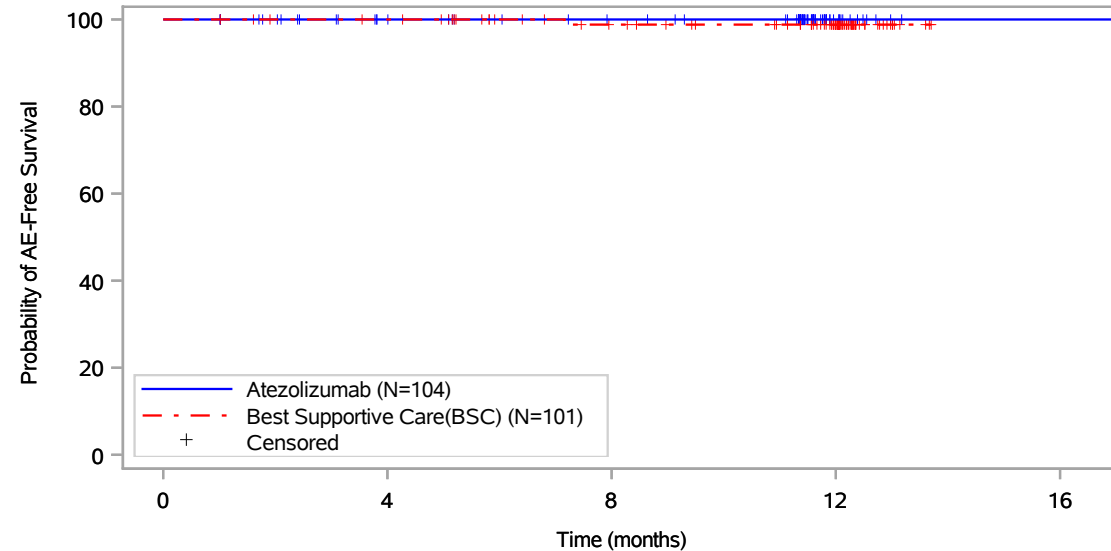
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Chest discomfort



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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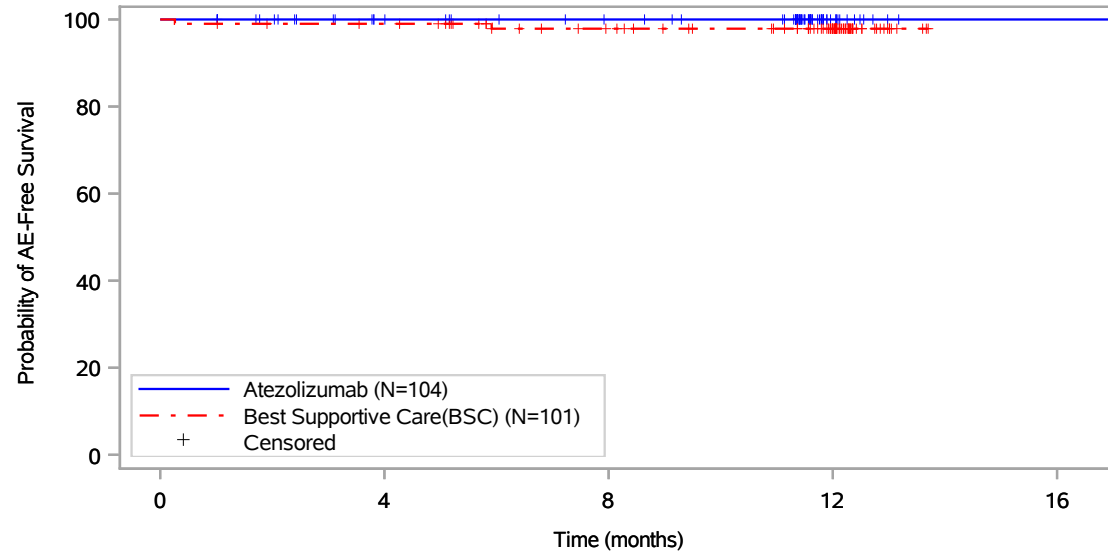
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Chest pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	3	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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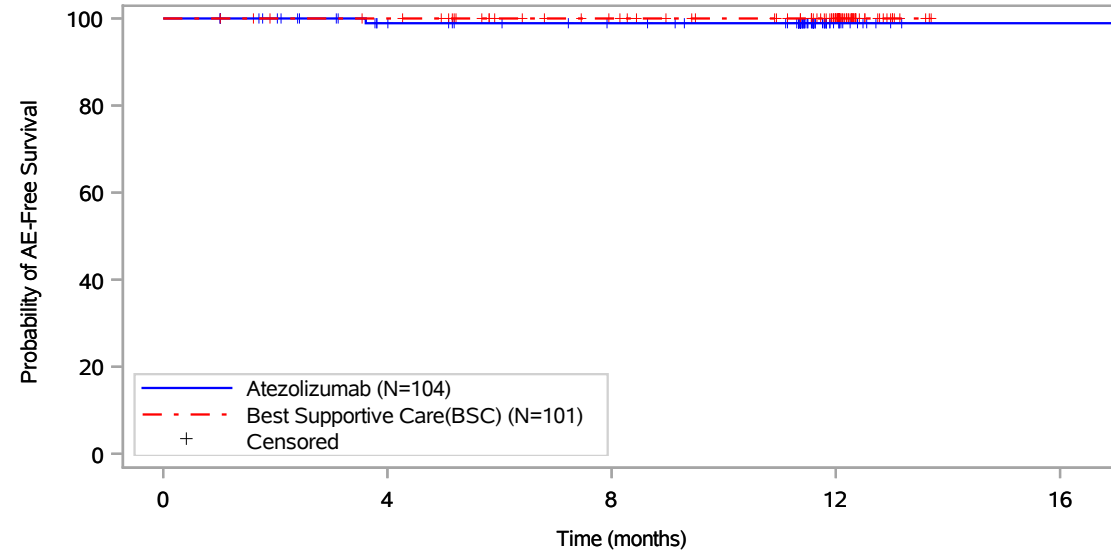
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Chills



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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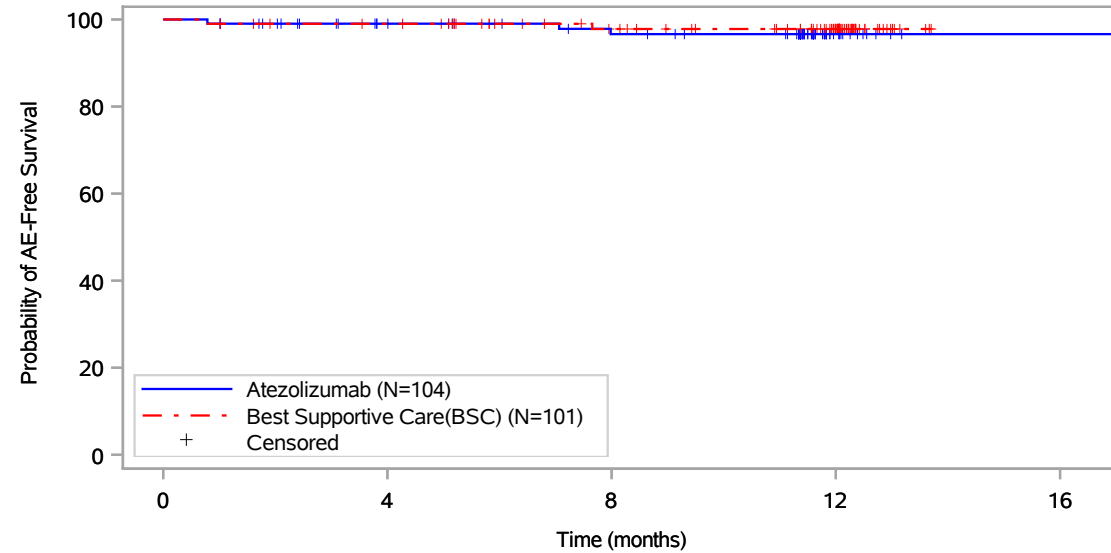
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	96	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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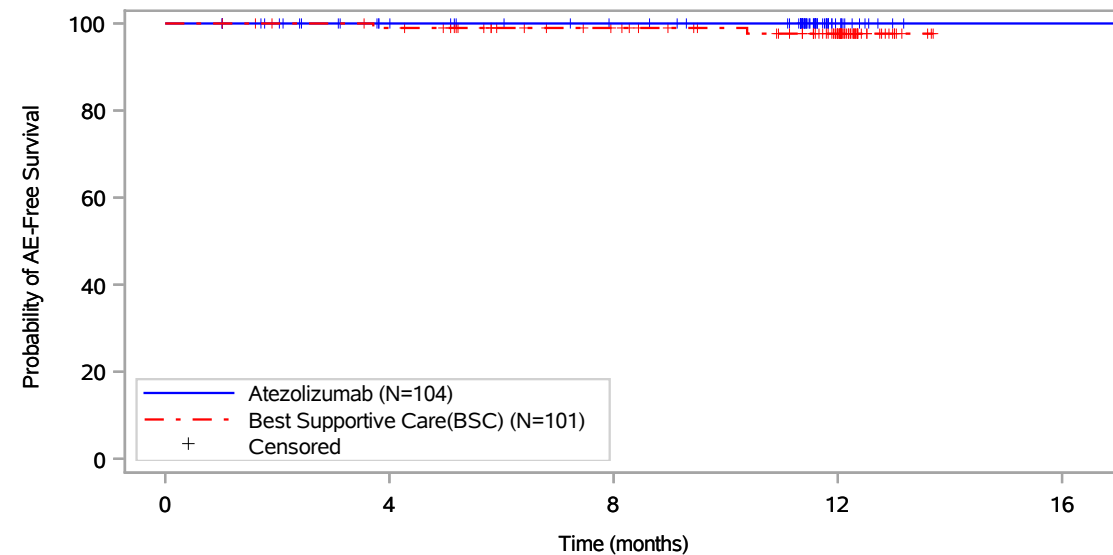
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Gait disturbance



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

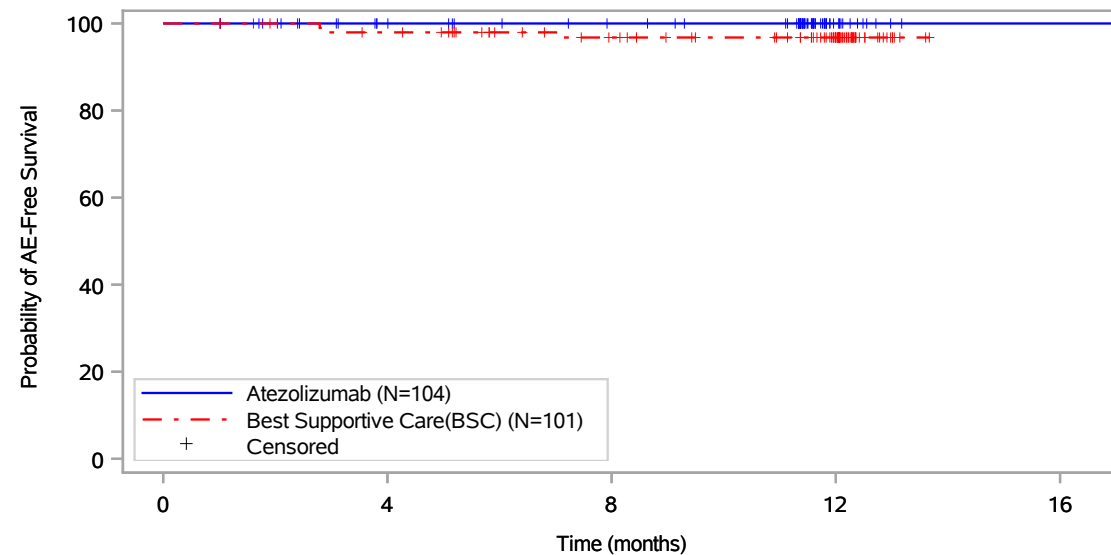
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	95	80	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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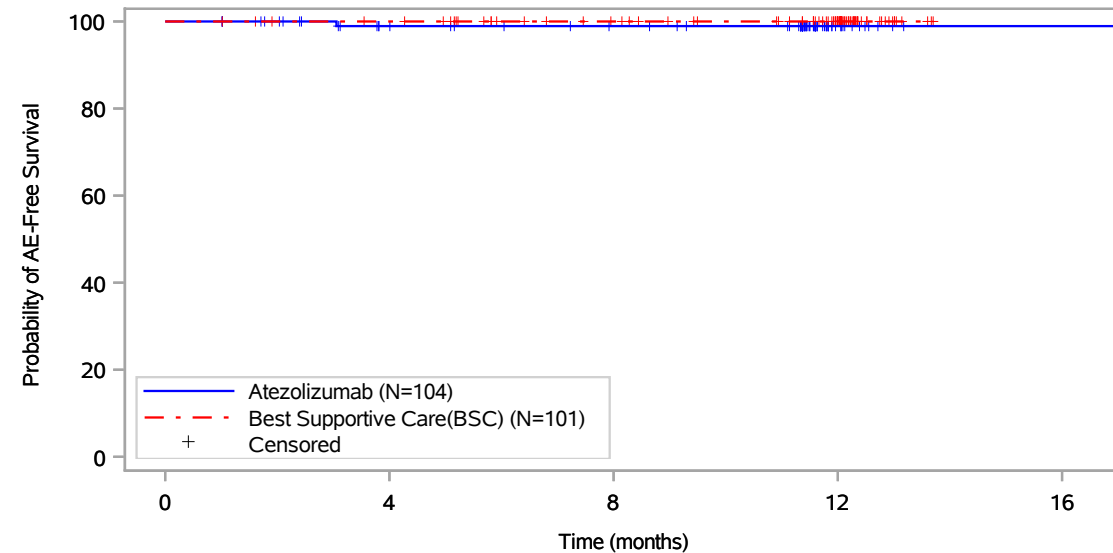
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Oedema



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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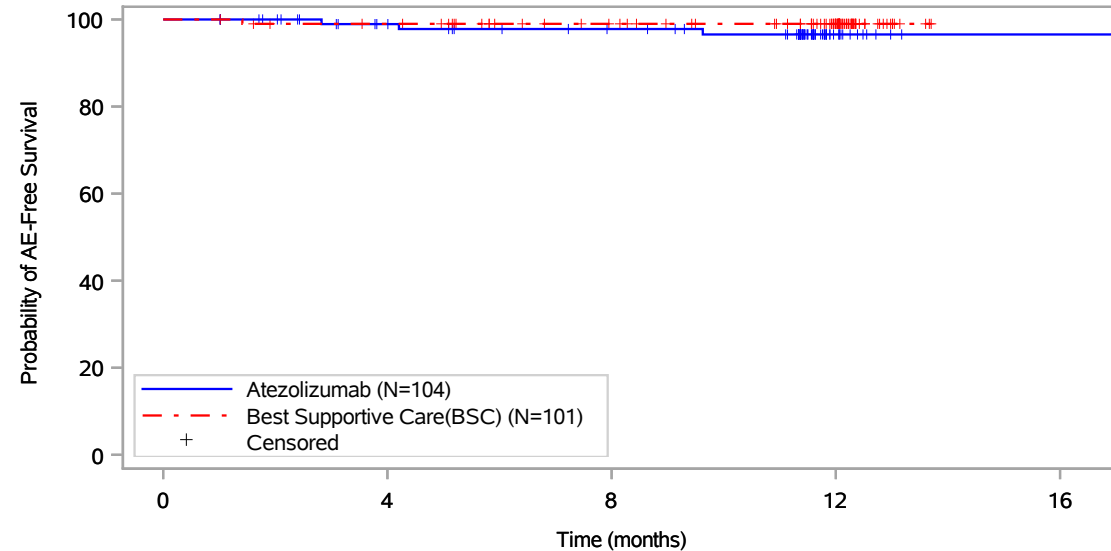
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Oedema peripheral



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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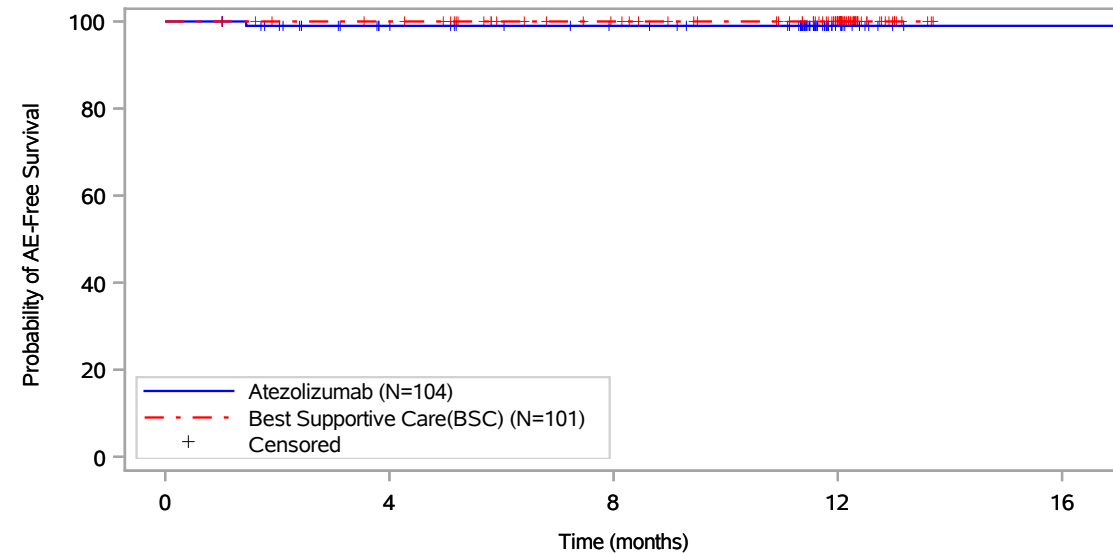
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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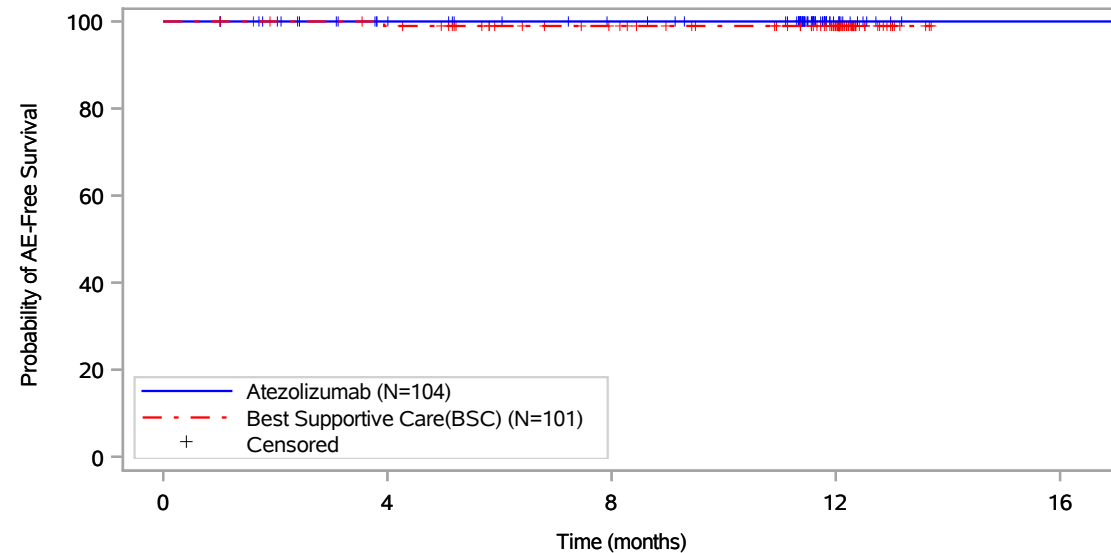
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Peripheral swelling



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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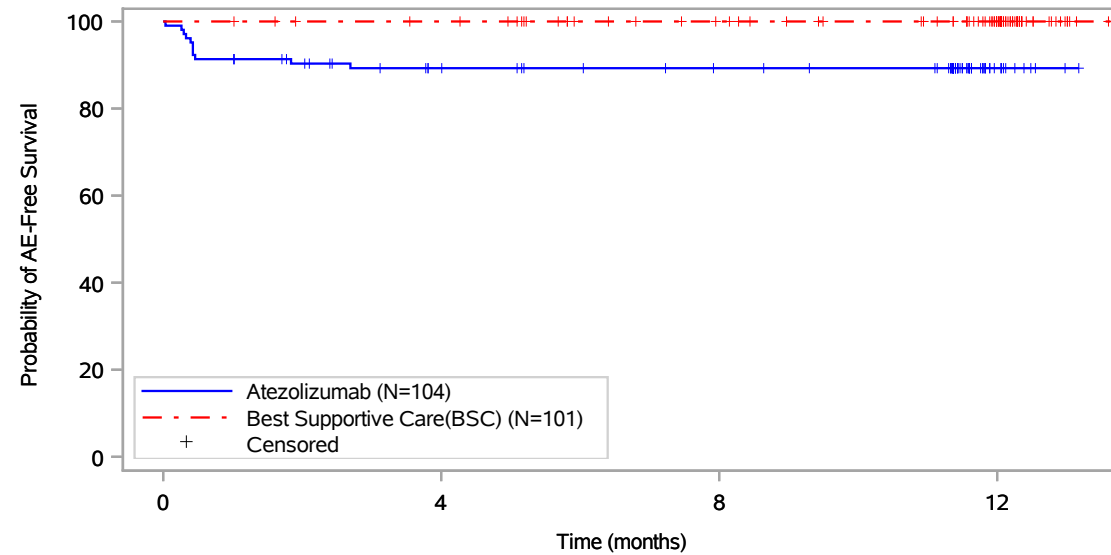
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Pyrexia



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	80	73	11
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	13	20	82
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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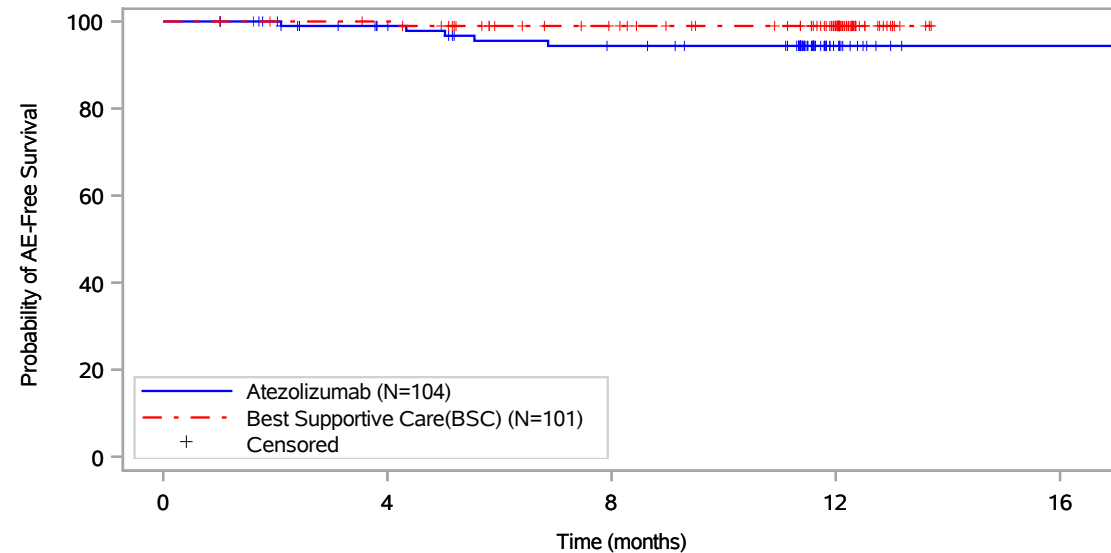
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	19	86	98
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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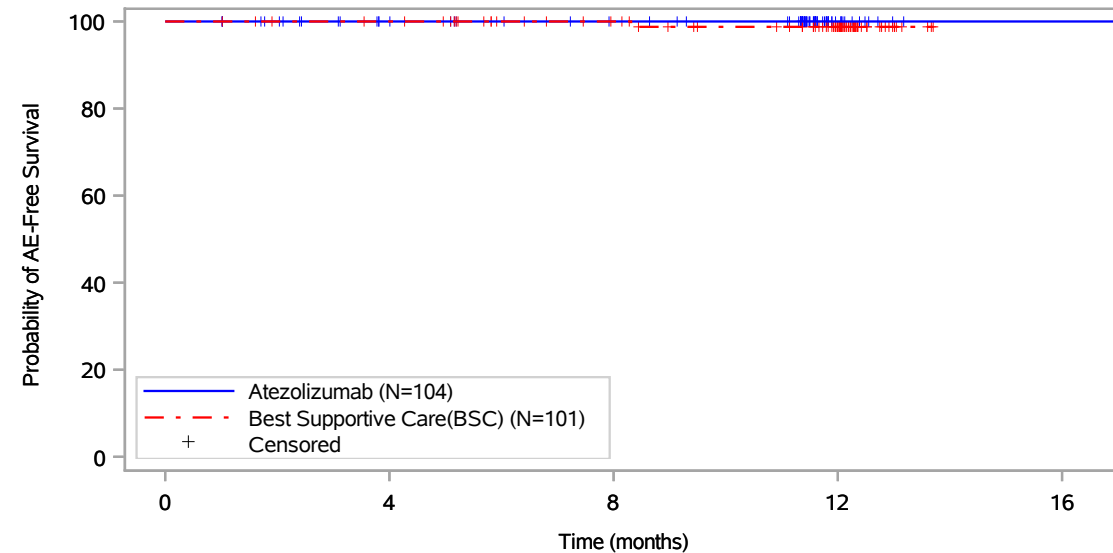
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Cholestasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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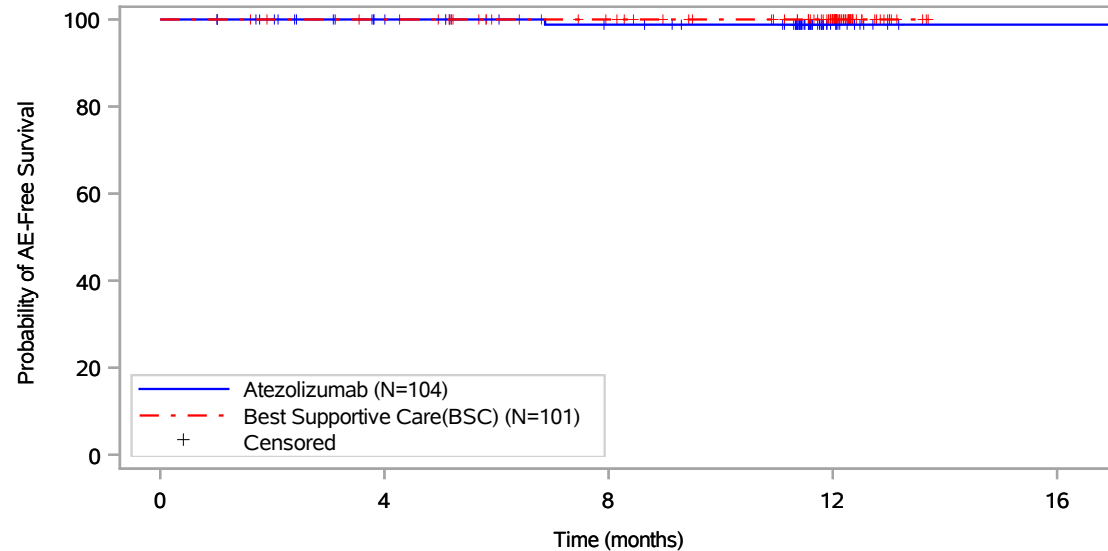
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Drug-induced liver injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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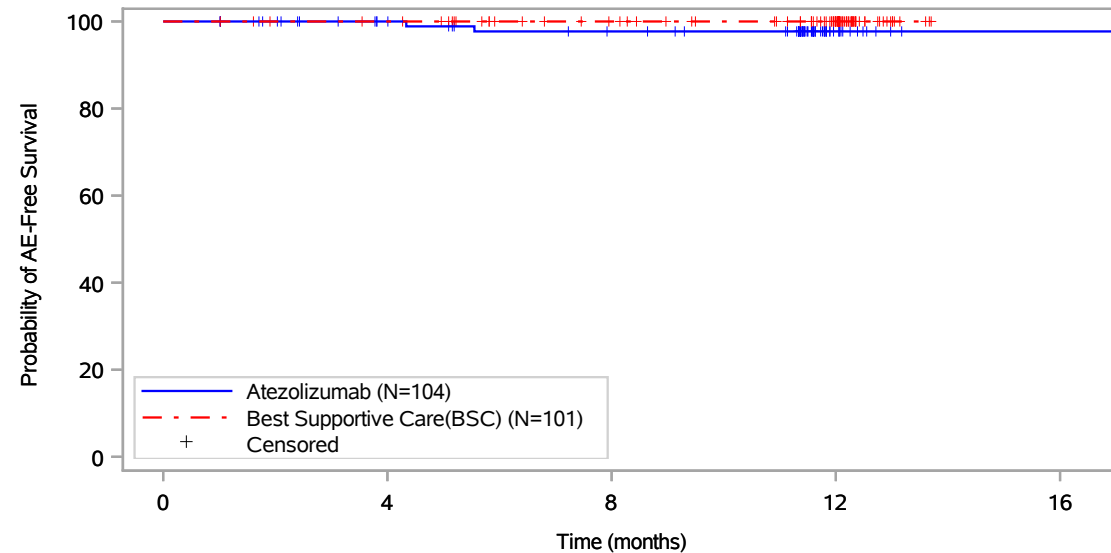
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



Patients at risk					
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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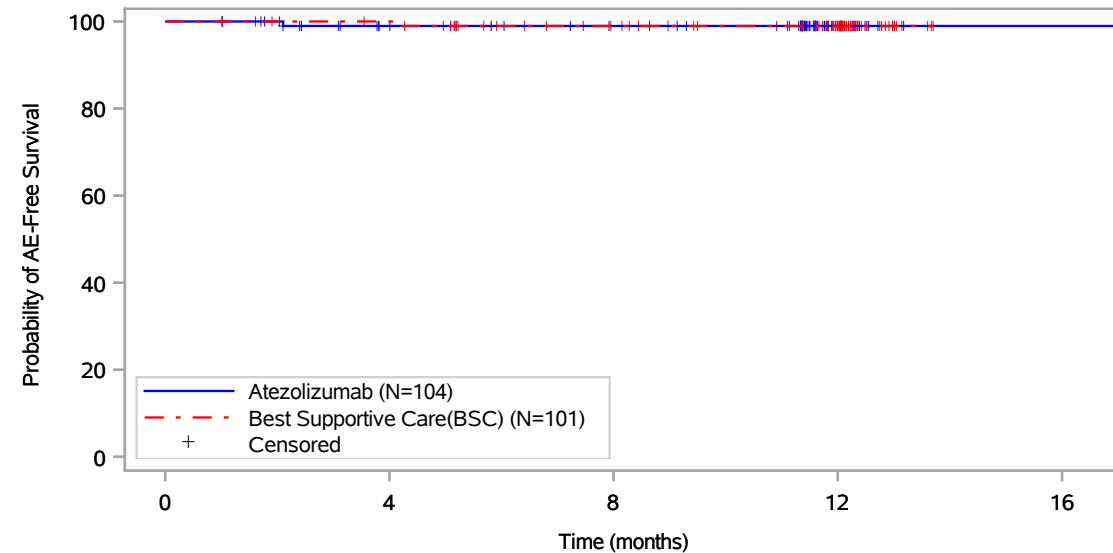
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Hepatic steatosis



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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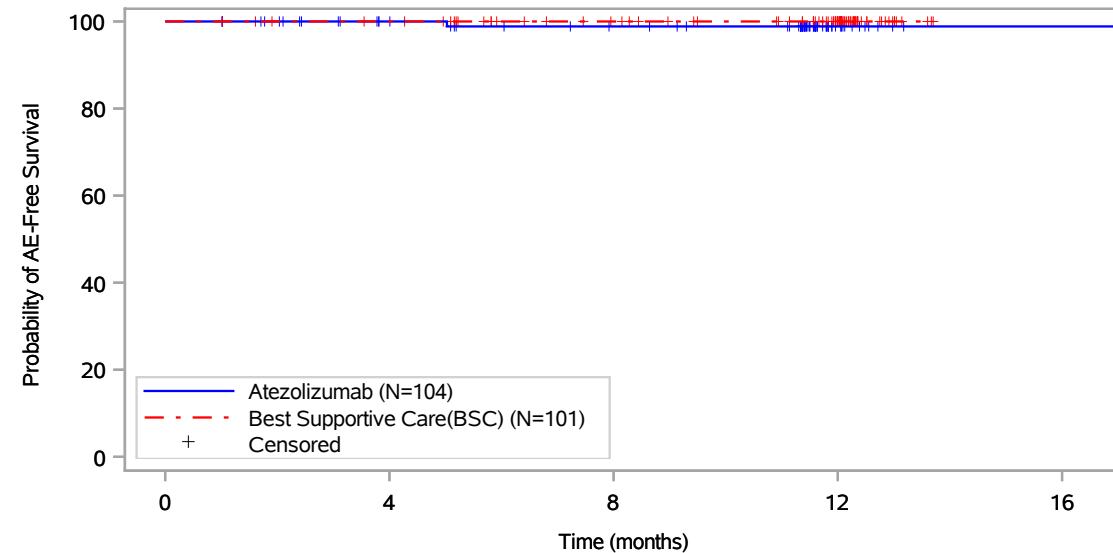
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Hyperbilirubinaemia



Patients at risk					
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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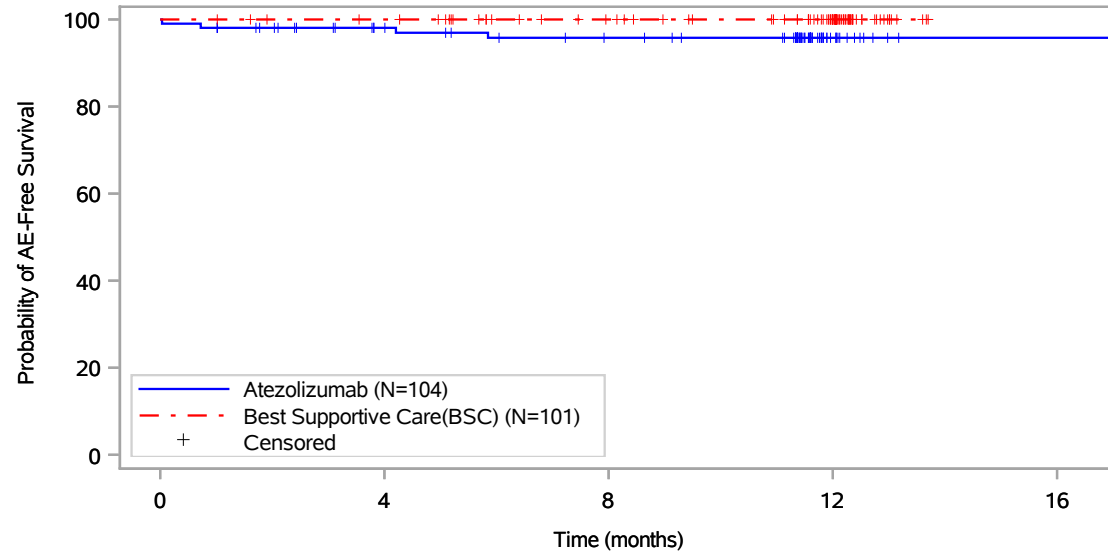
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Immune system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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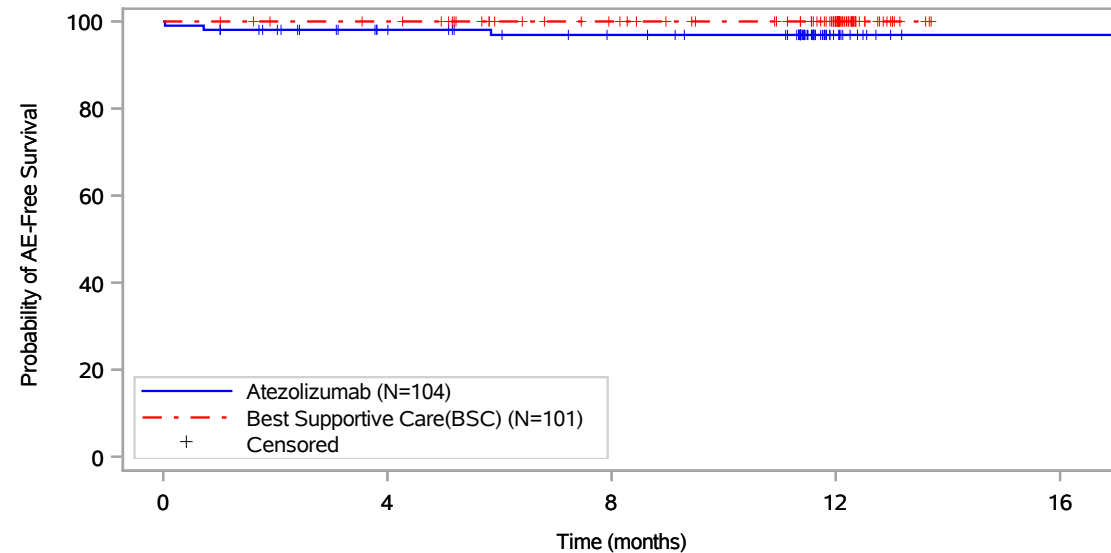
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Immune system disorders, Hypersensitivity



Patients at risk					
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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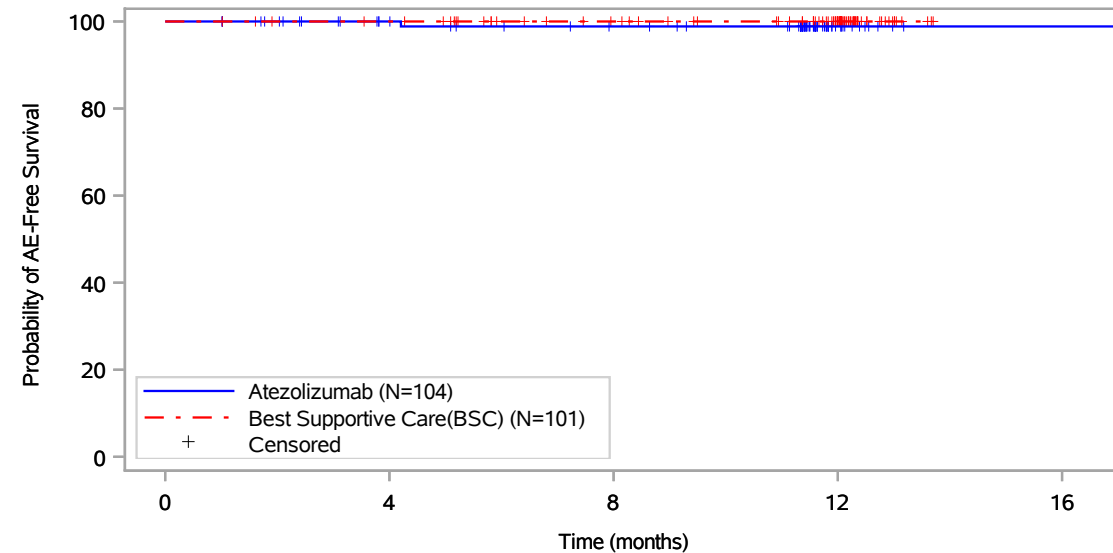
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Immune system disorders, Sarcoidosis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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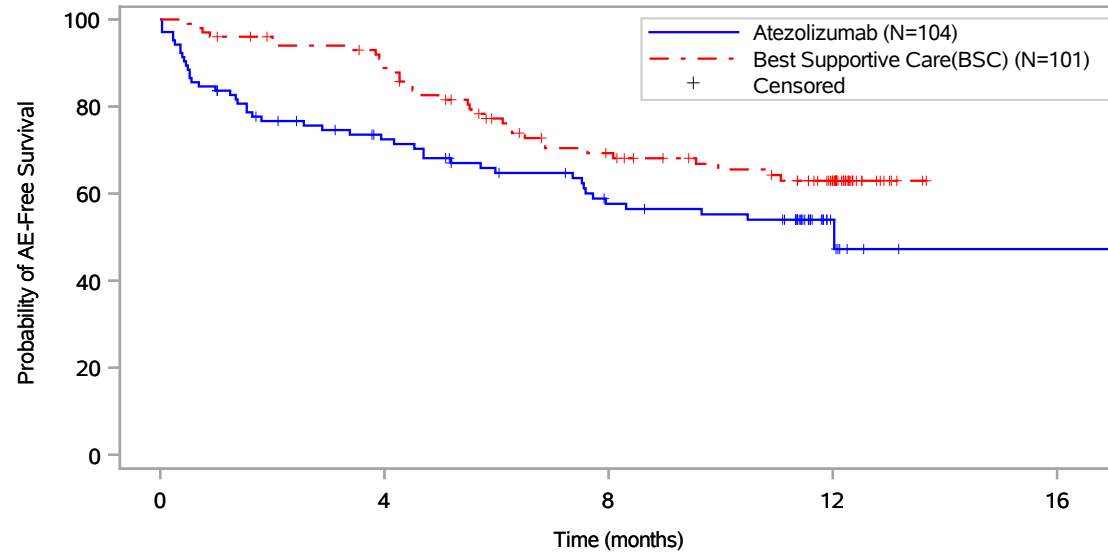
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	67	48	8	1
Best Supportive Care(BSC) (N=101)	101	86	59	36	NE
Patients censored					
Atezolizumab (N=104)	0	9	15	52	58
Best Supportive Care(BSC) (N=101)	0	4	13	31	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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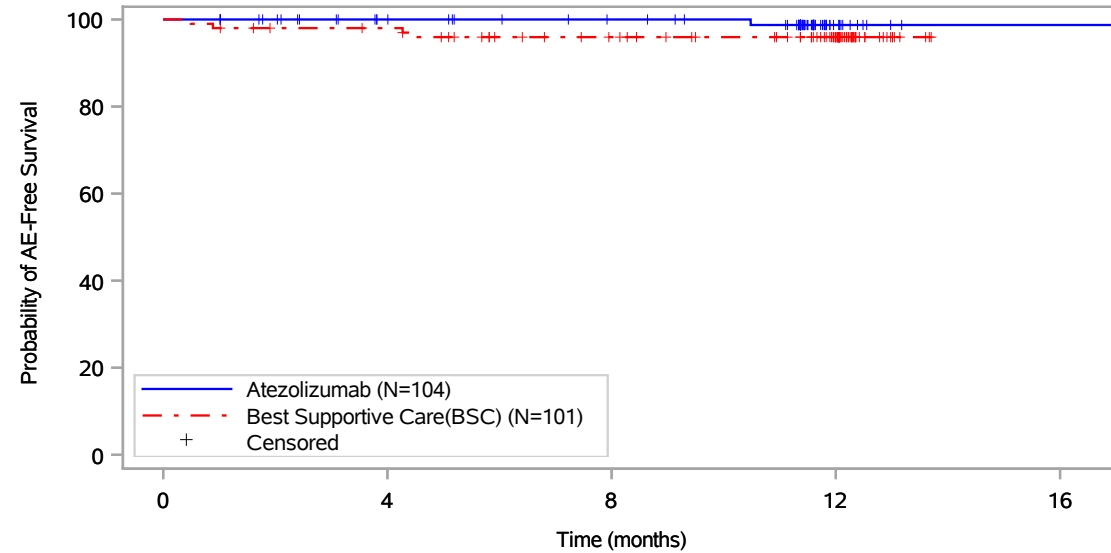
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Bronchitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	95	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	16	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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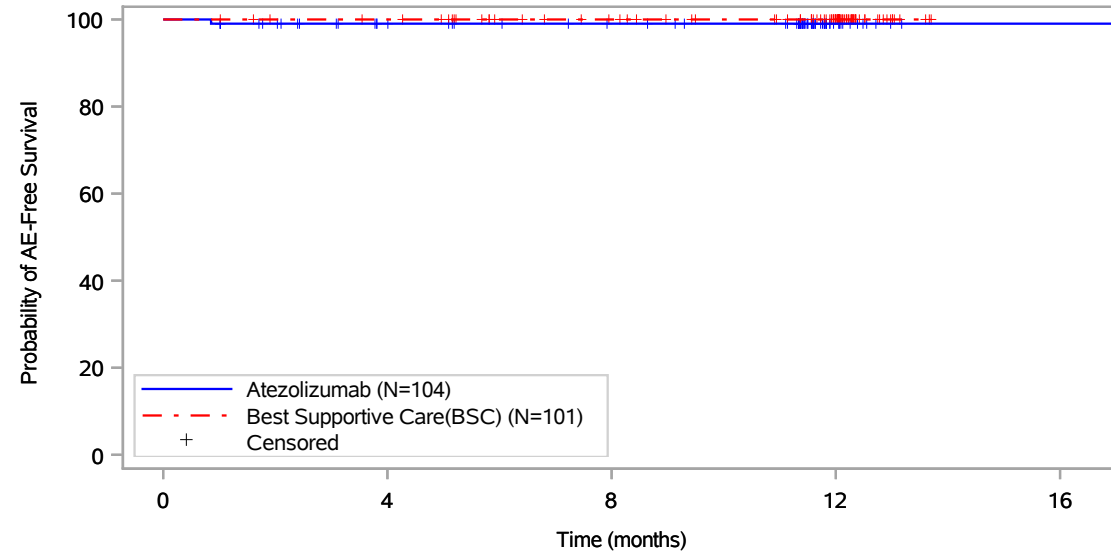
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Candida infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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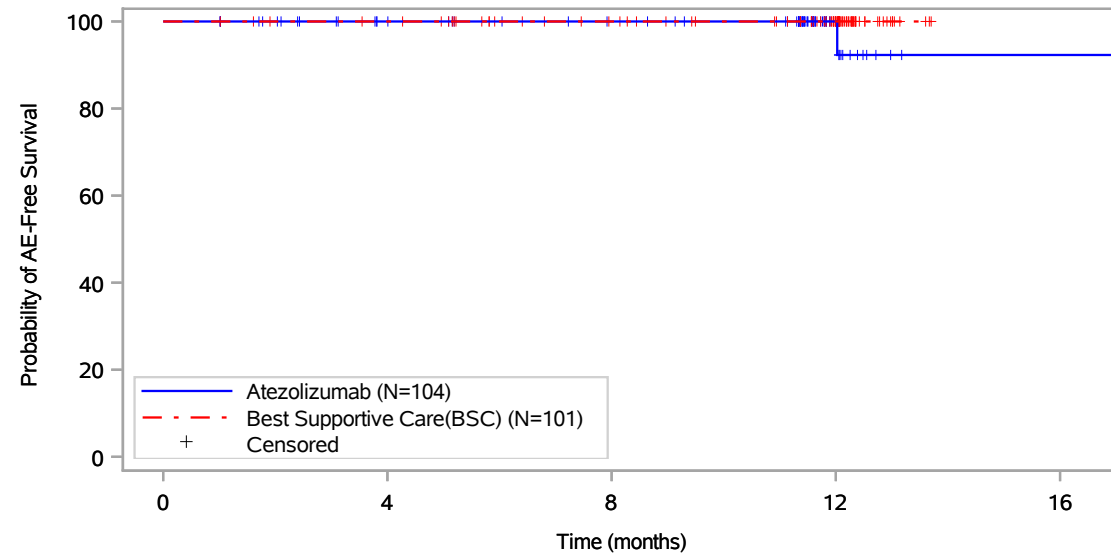
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Cellulitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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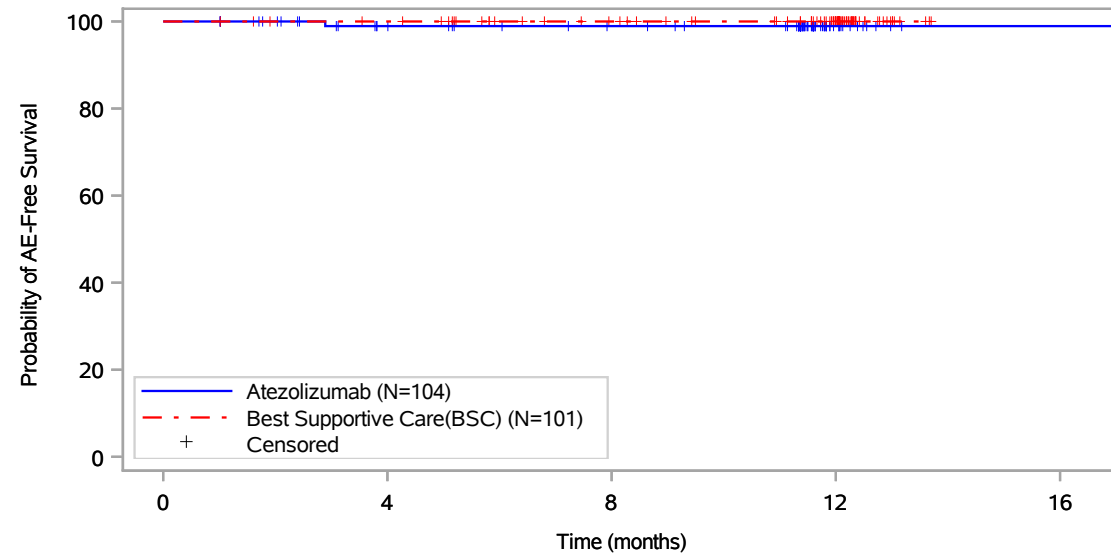
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Conjunctivitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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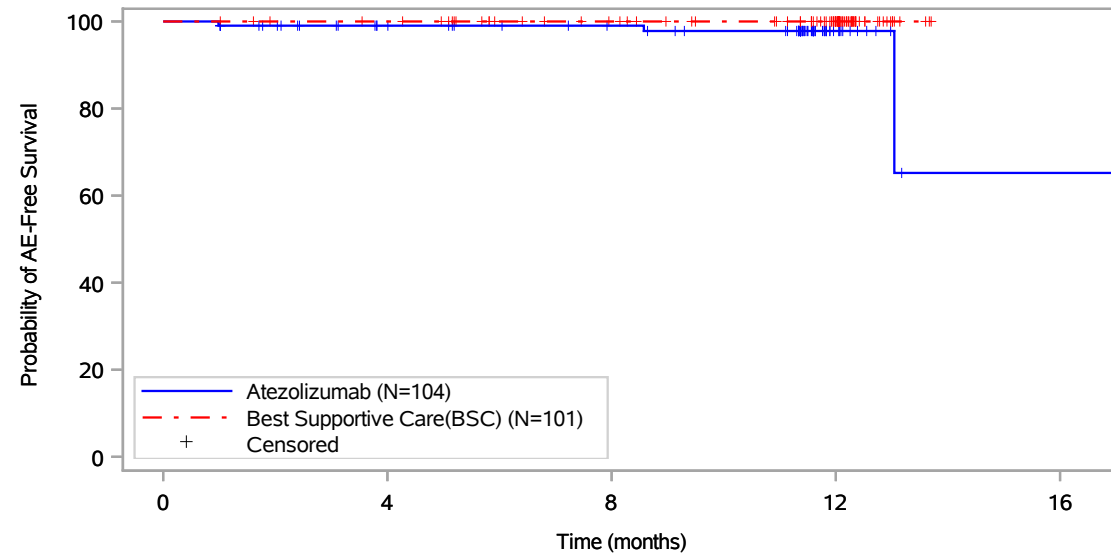
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Cystitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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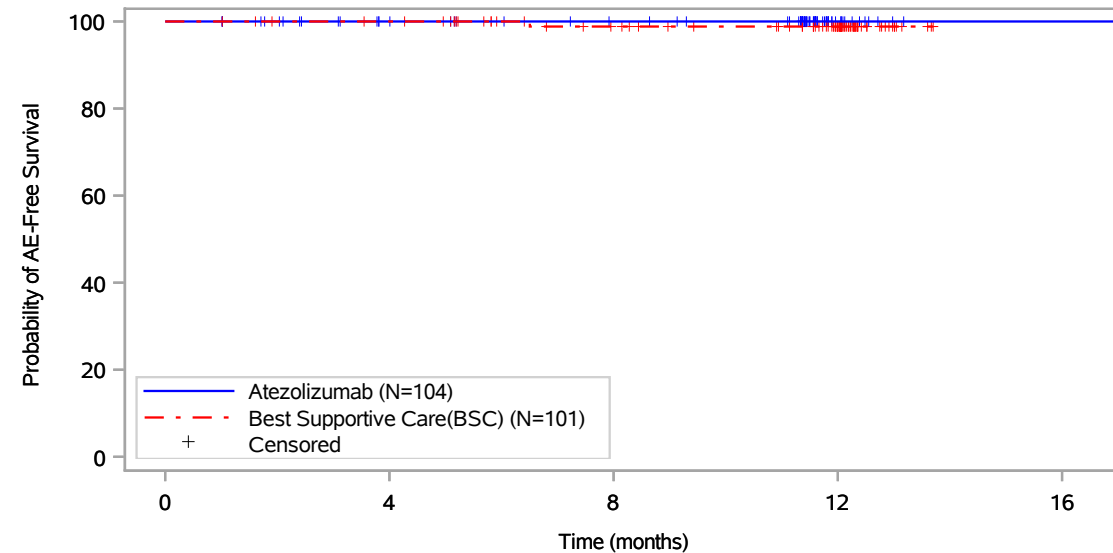
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Empyema



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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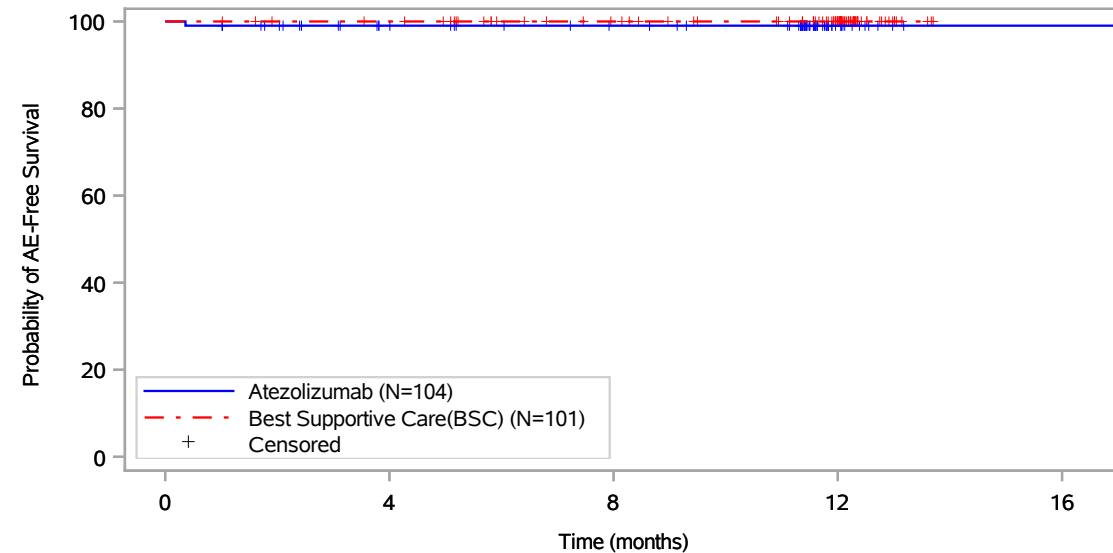
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Encephalitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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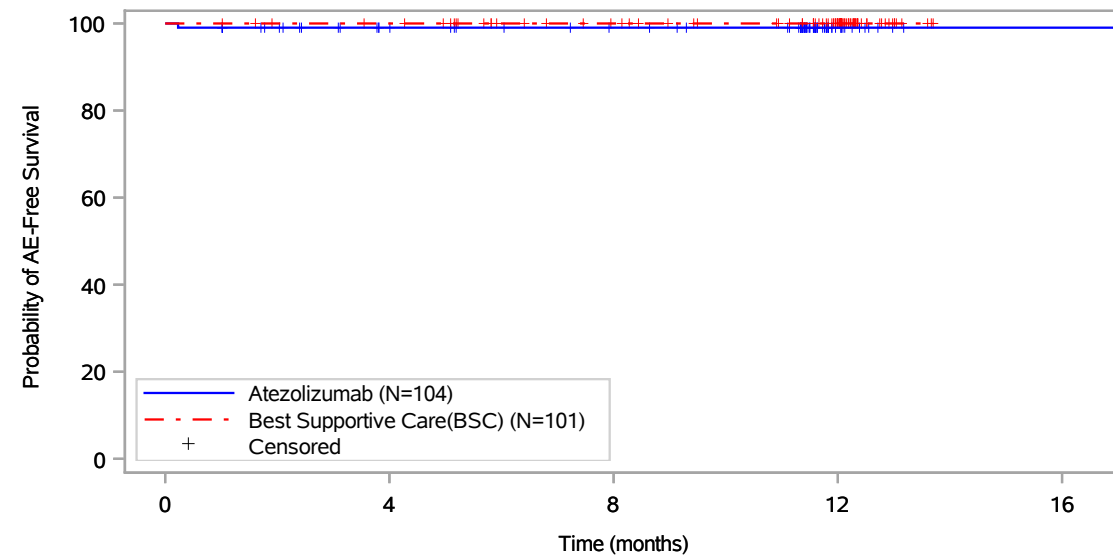
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Fungal pharyngitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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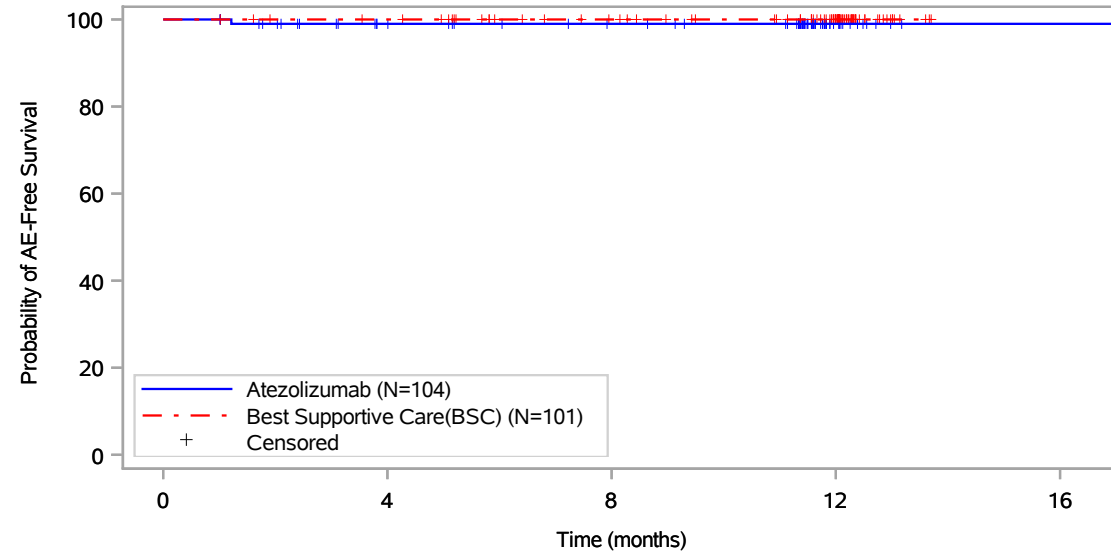
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Furuncle



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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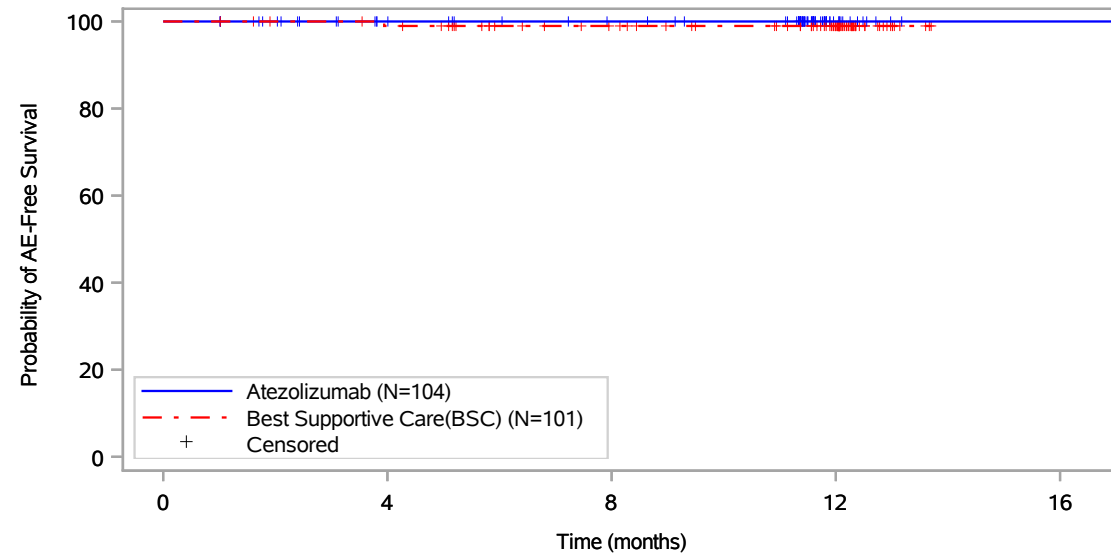
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Gastroenteritis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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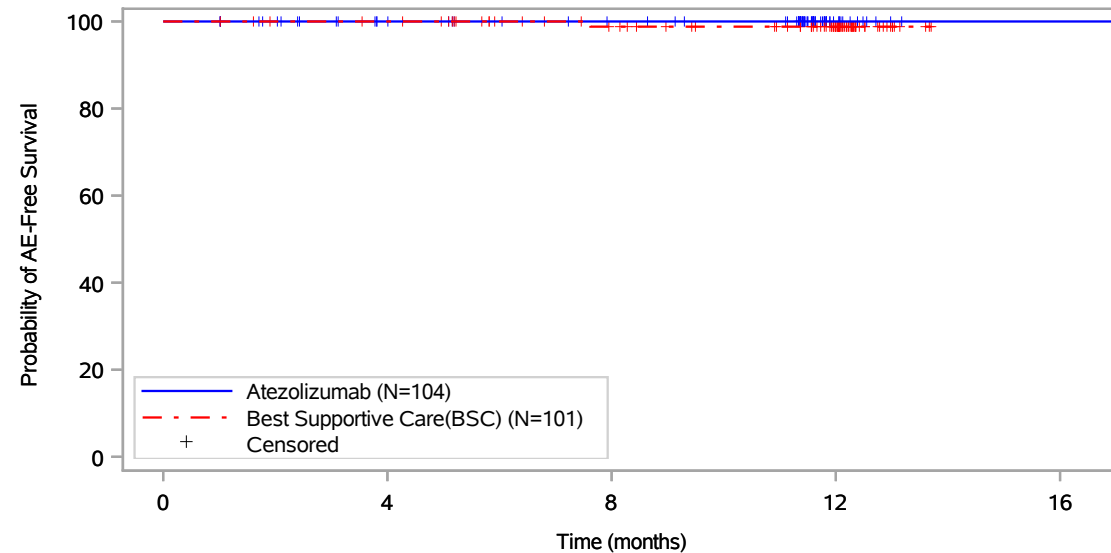
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Gastrointestinal bacterial overgrowth



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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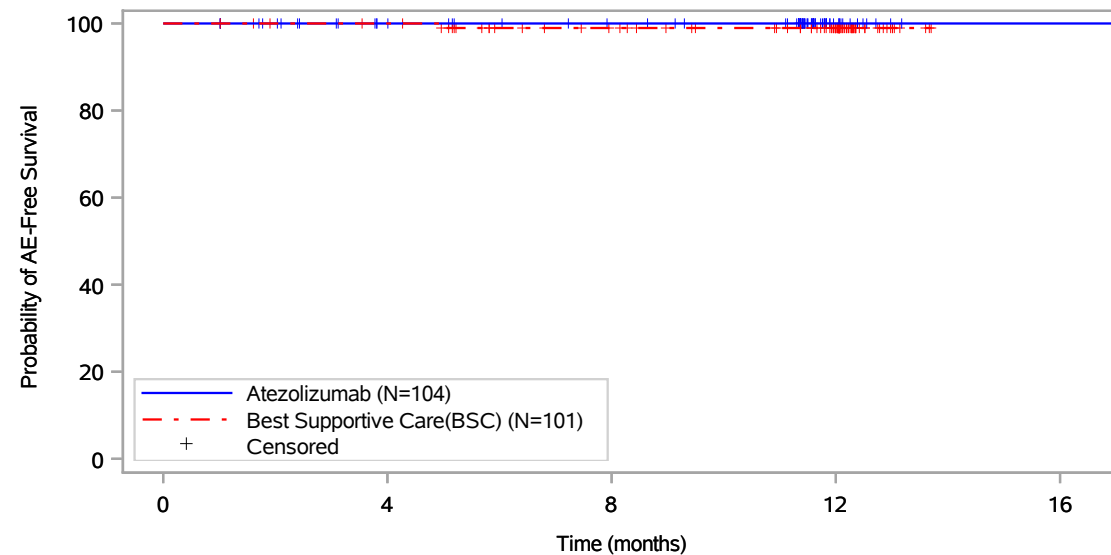
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Herpes zoster



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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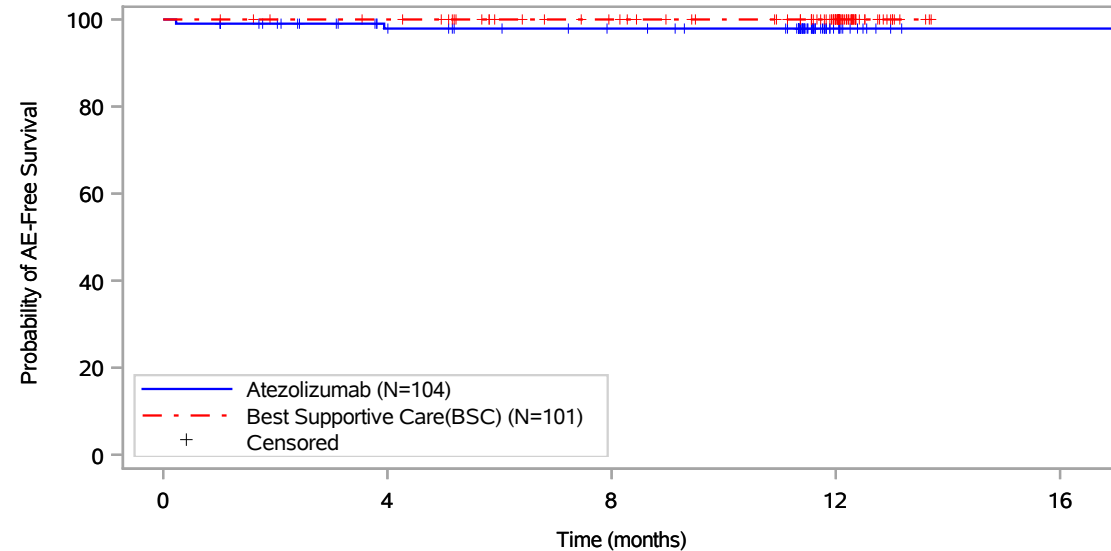
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Infectious pleural effusion



Patients at risk					
Atezolizumab (N=104)	104	87	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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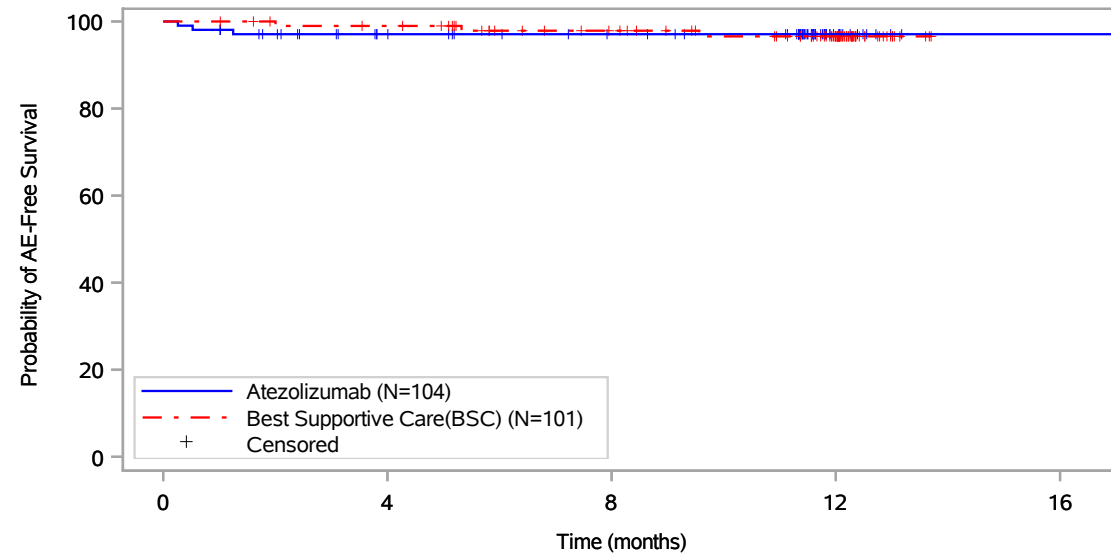
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Influenza



Patients at risk					
Atezolizumab (N=104)	104	86	79	13	1
Best Supportive Care(BSC) (N=101)	101	96	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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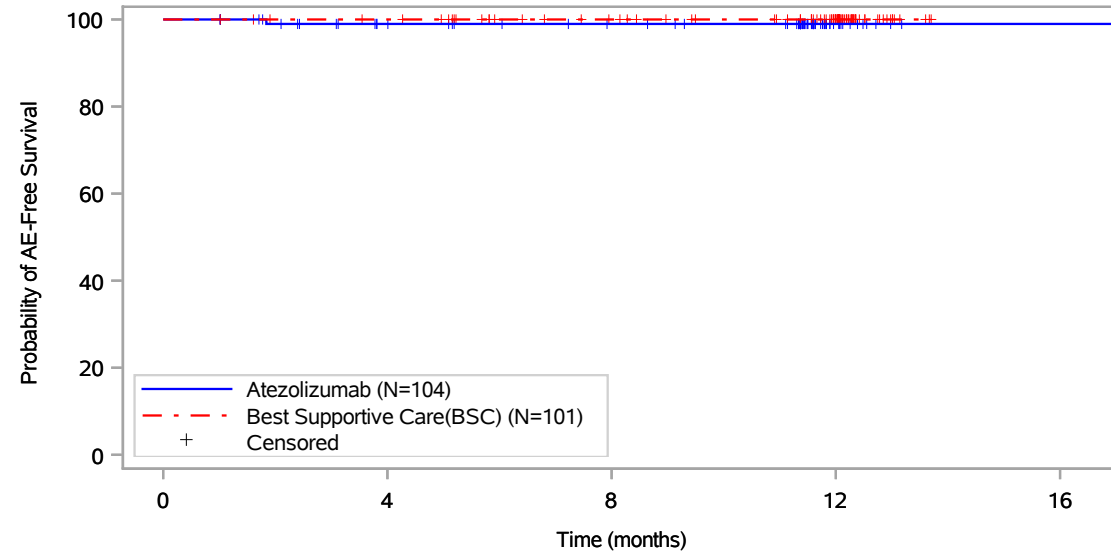
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Kidney infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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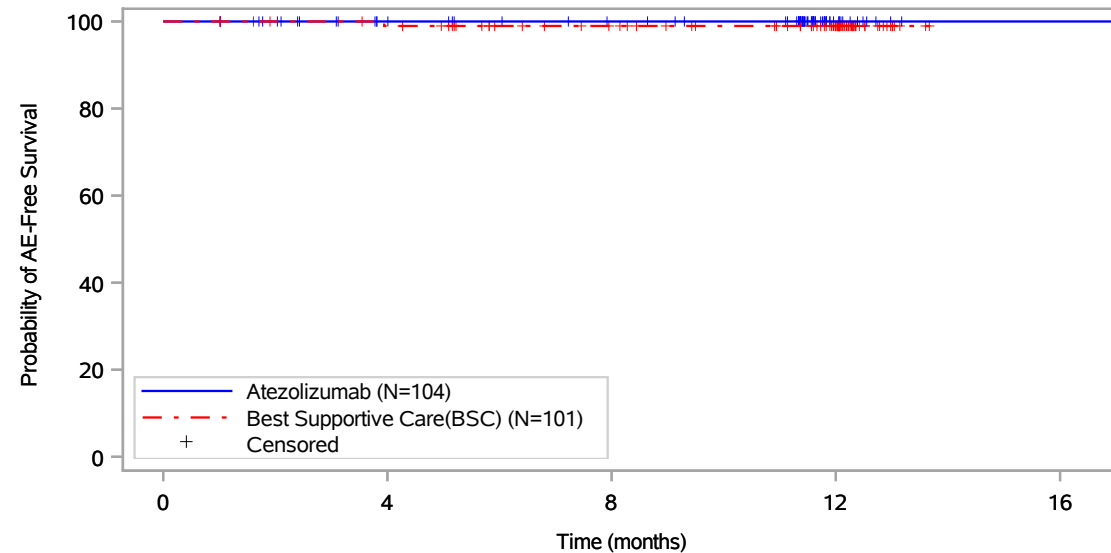
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Laryngitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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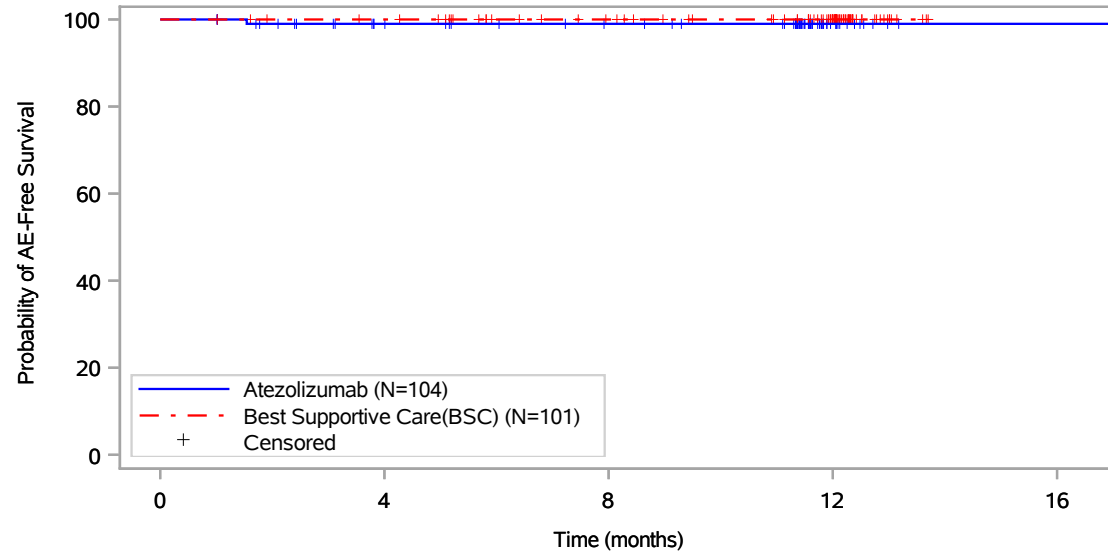
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Meningitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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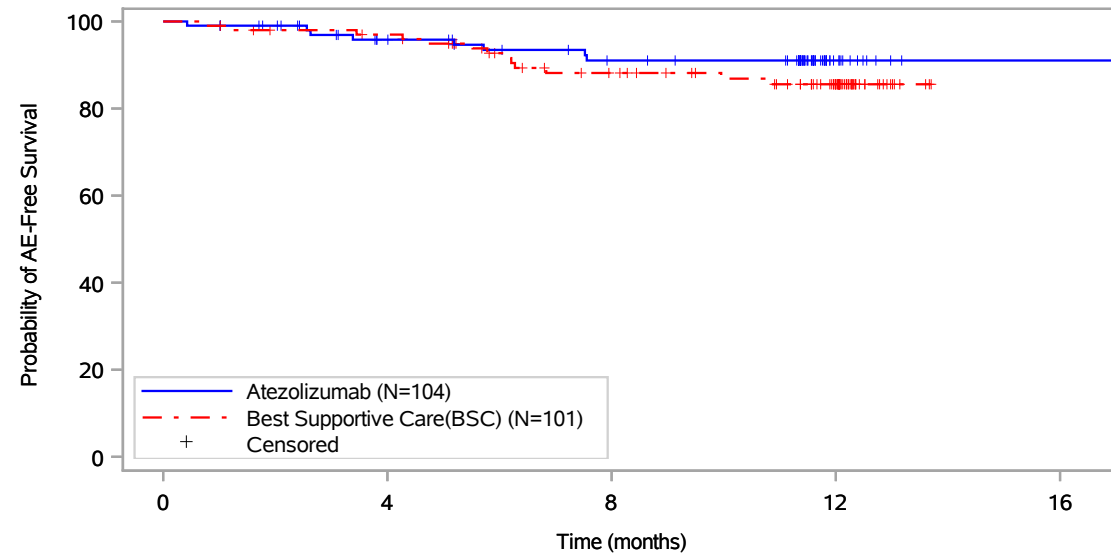
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Nasopharyngitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	85	74	12	1
Best Supportive Care(BSC) (N=101)	101	94	74	47	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	84	95
Best Supportive Care(BSC) (N=101)	0	4	16	41	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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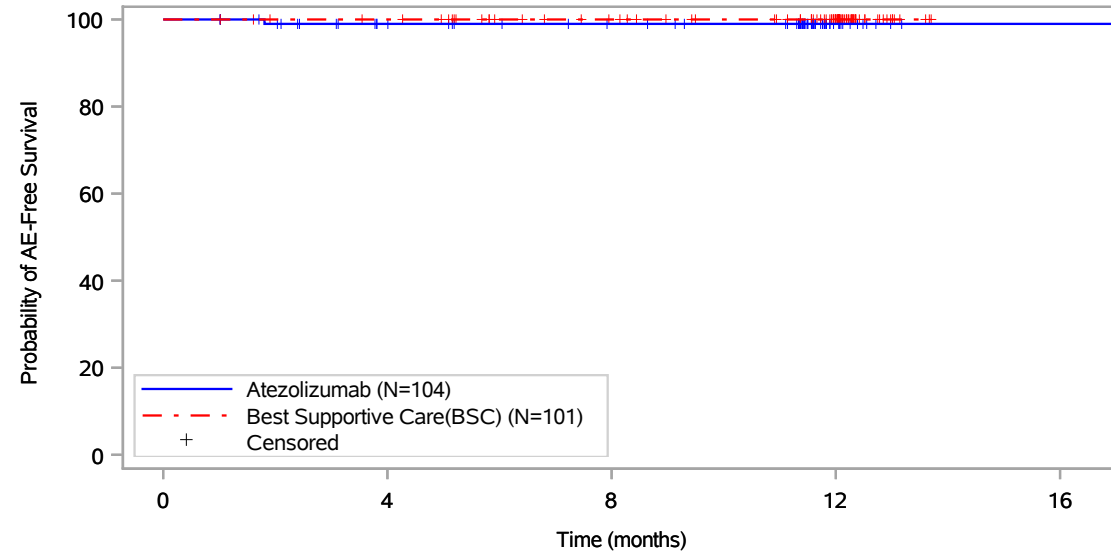
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Oral fungal infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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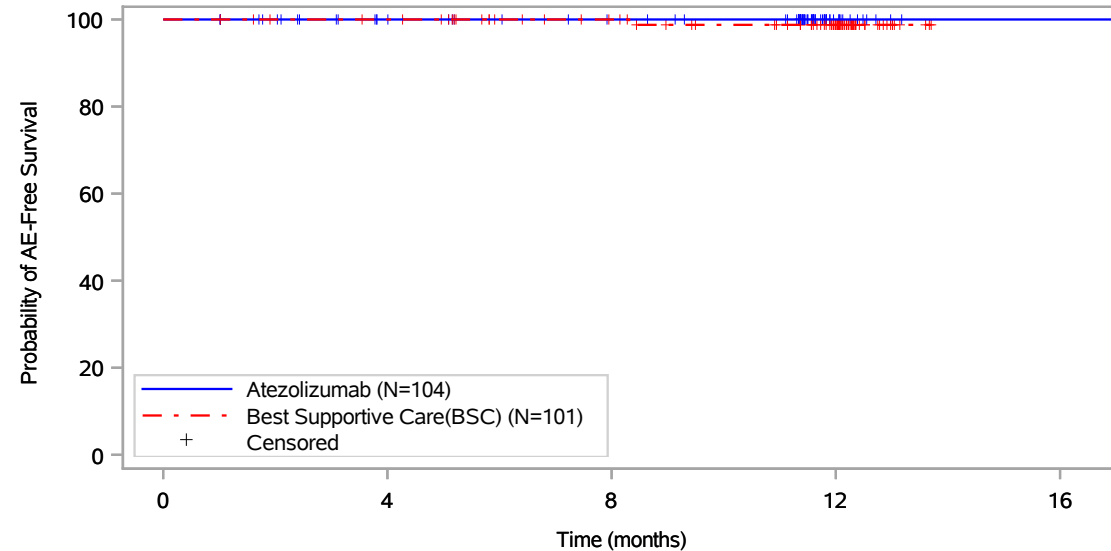
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Oral herpes



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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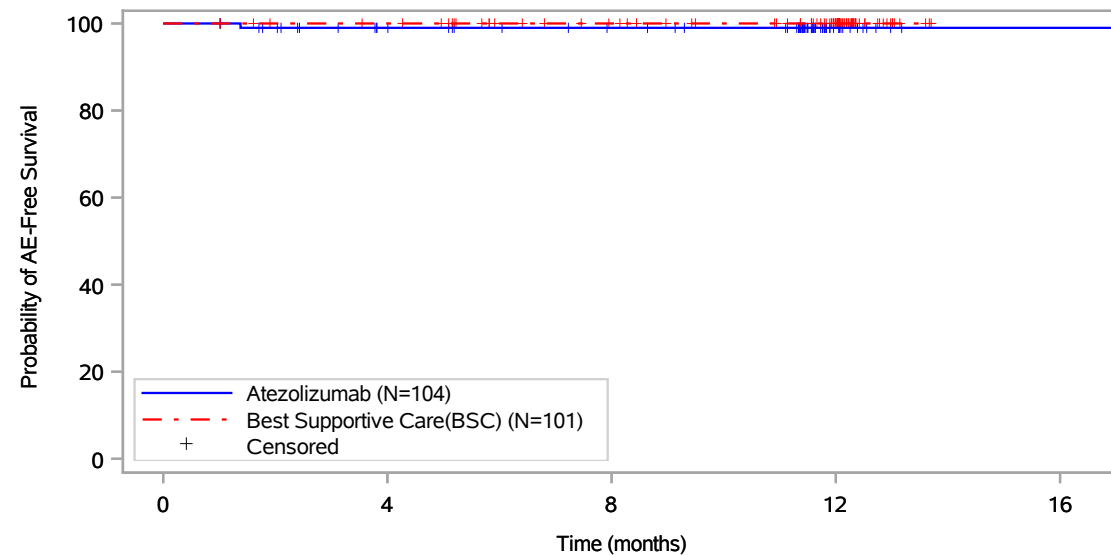
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Otitis externa



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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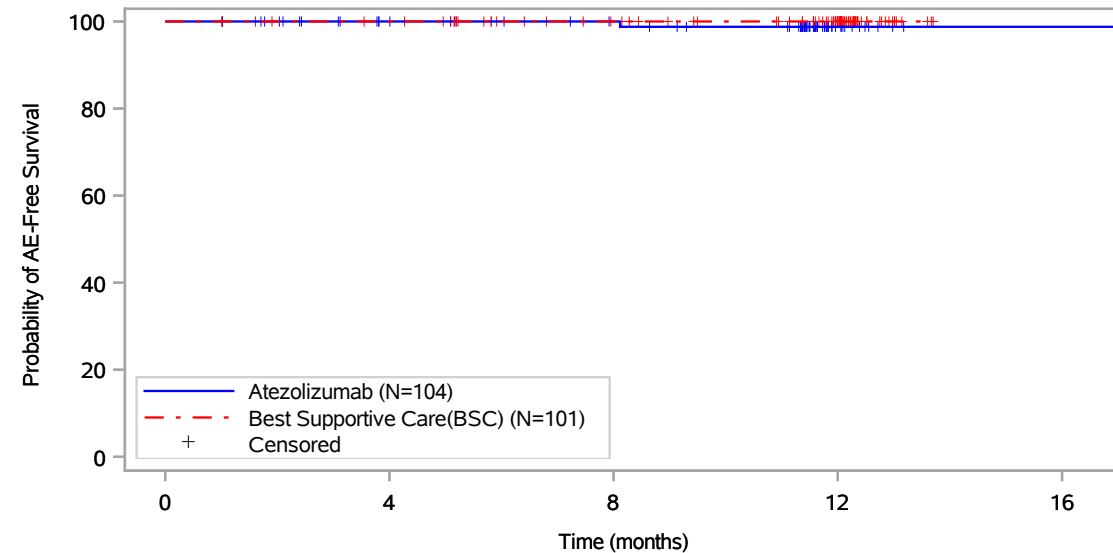
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Otitis media



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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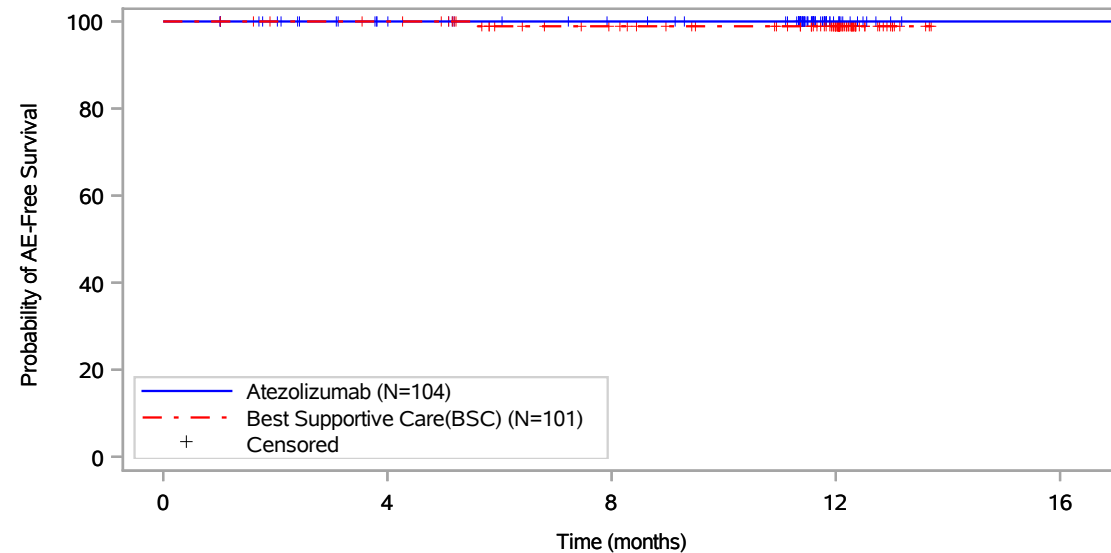
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Paronychia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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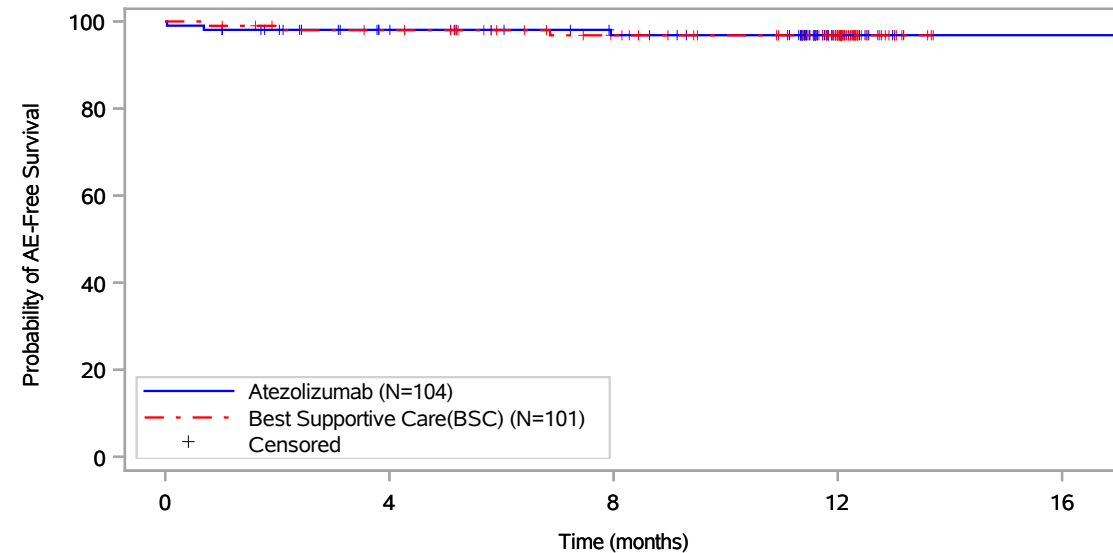
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Pharyngitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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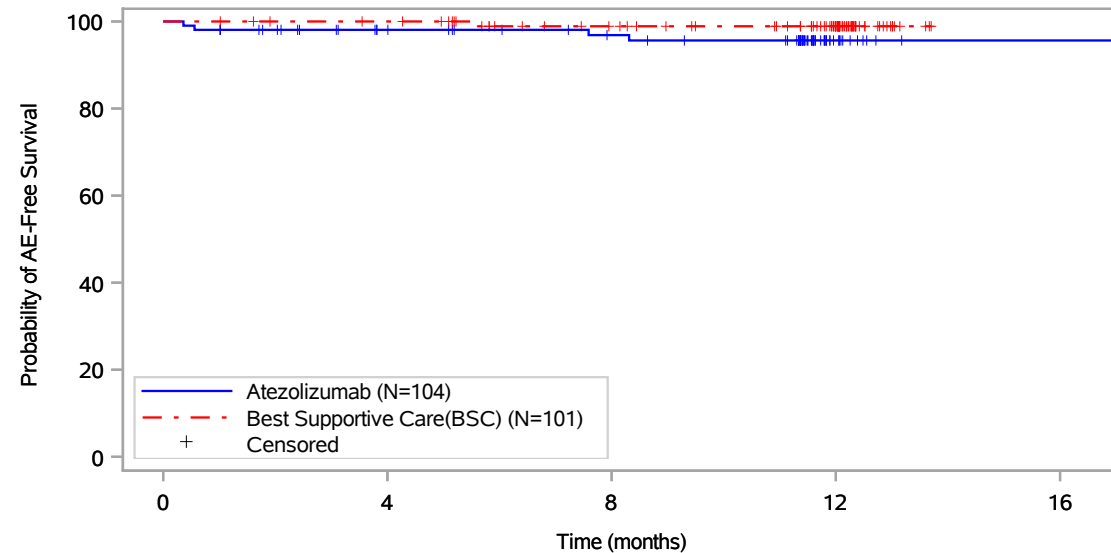
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Pneumonia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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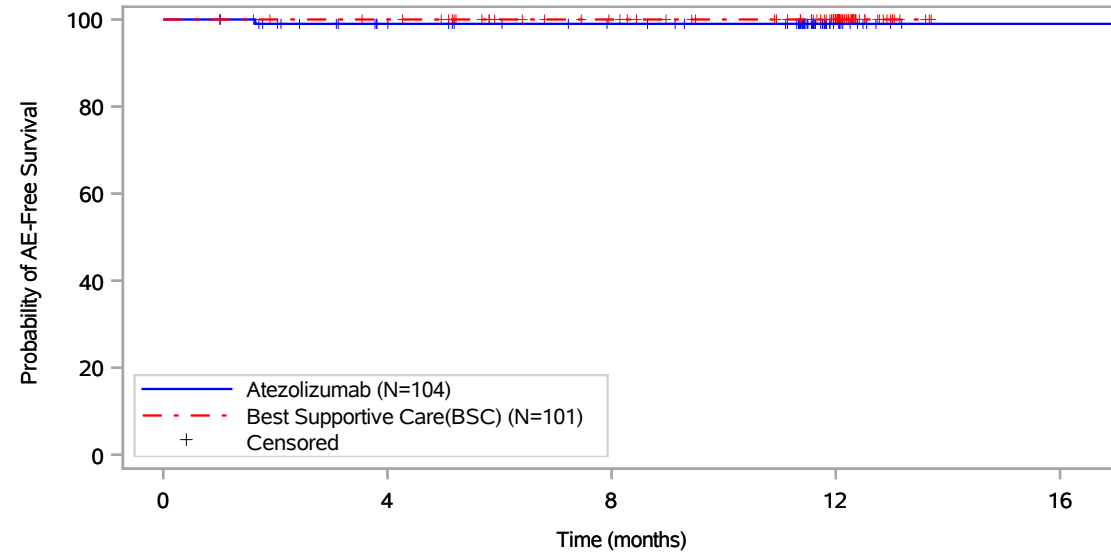
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Pneumonia pneumococcal



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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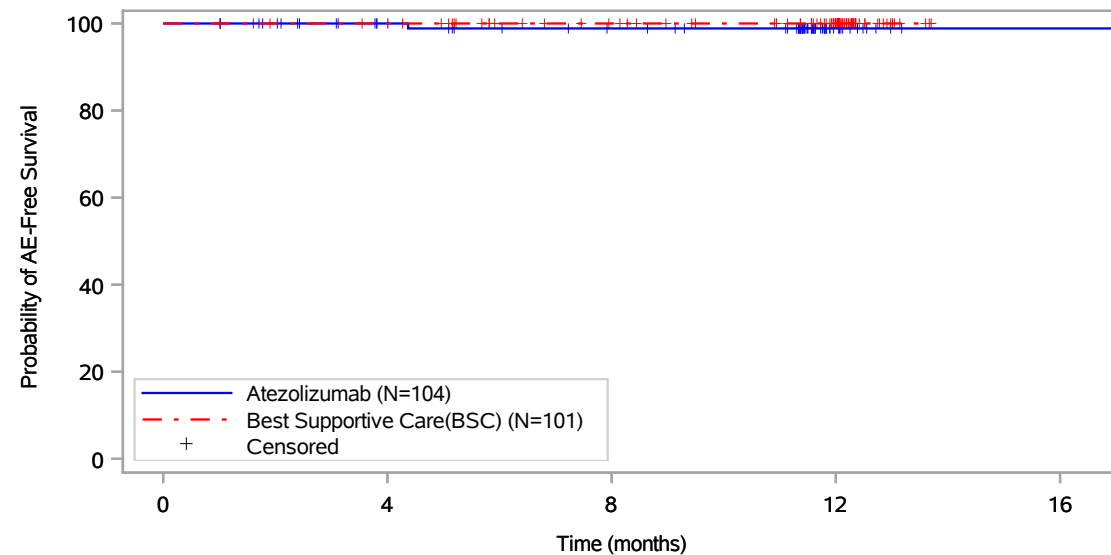
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Prostate infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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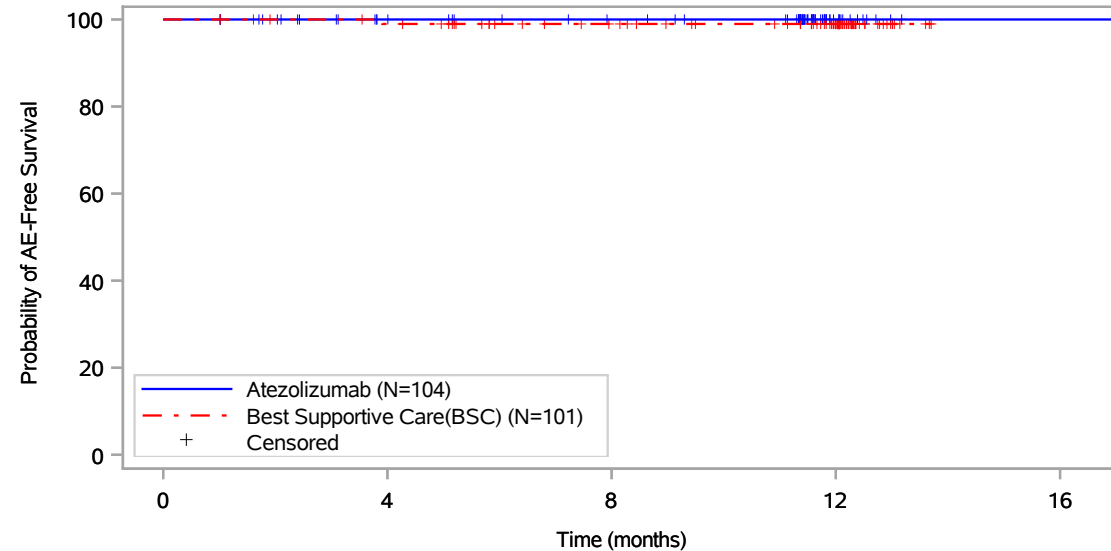
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Pulpitis dental



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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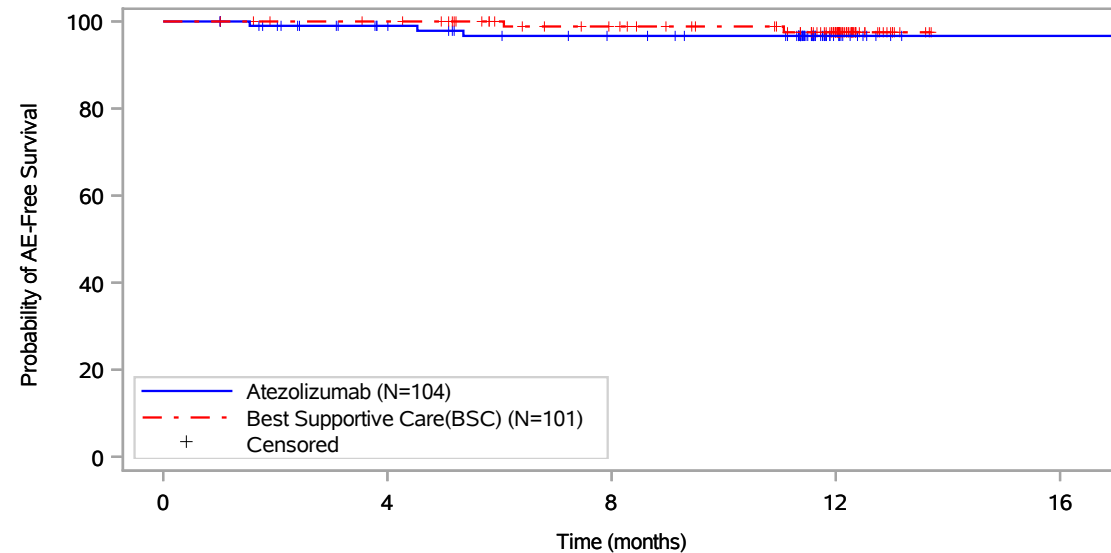
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Respiratory tract infection



Patients at risk					
Atezolizumab (N=104)	104	88	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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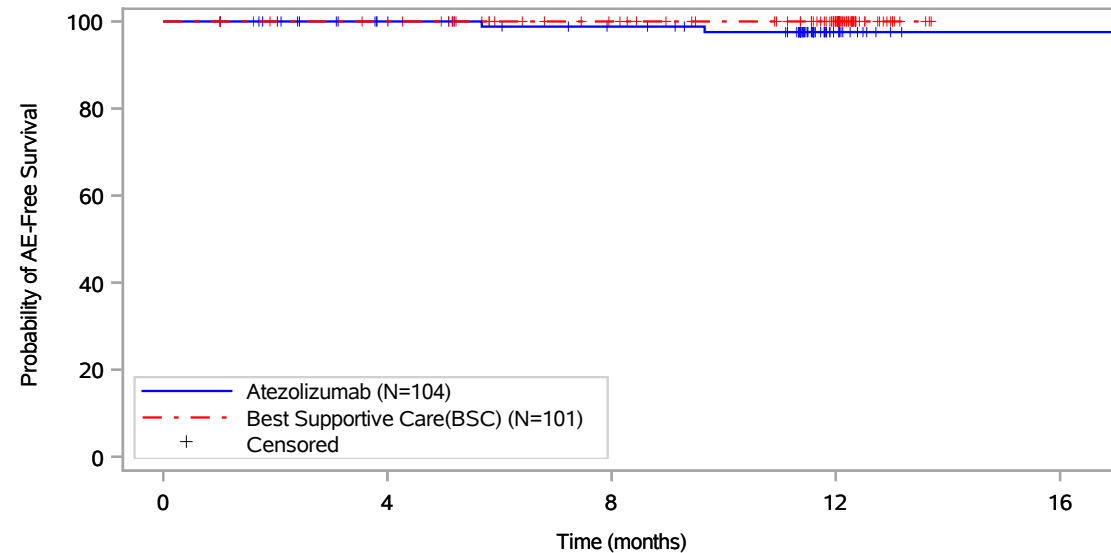
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Respiratory tract infection viral



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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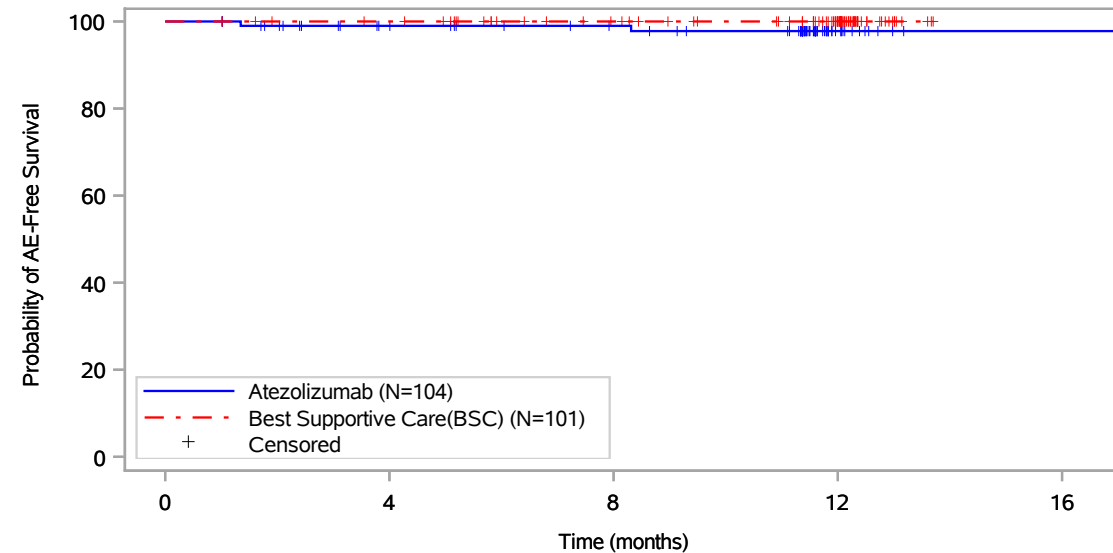
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Rhinitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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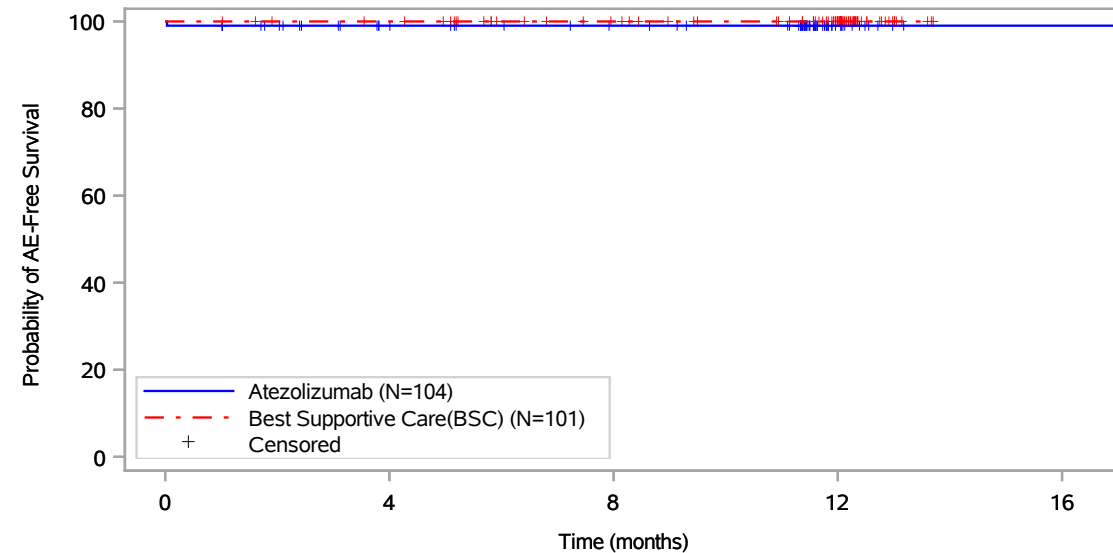
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Sepsis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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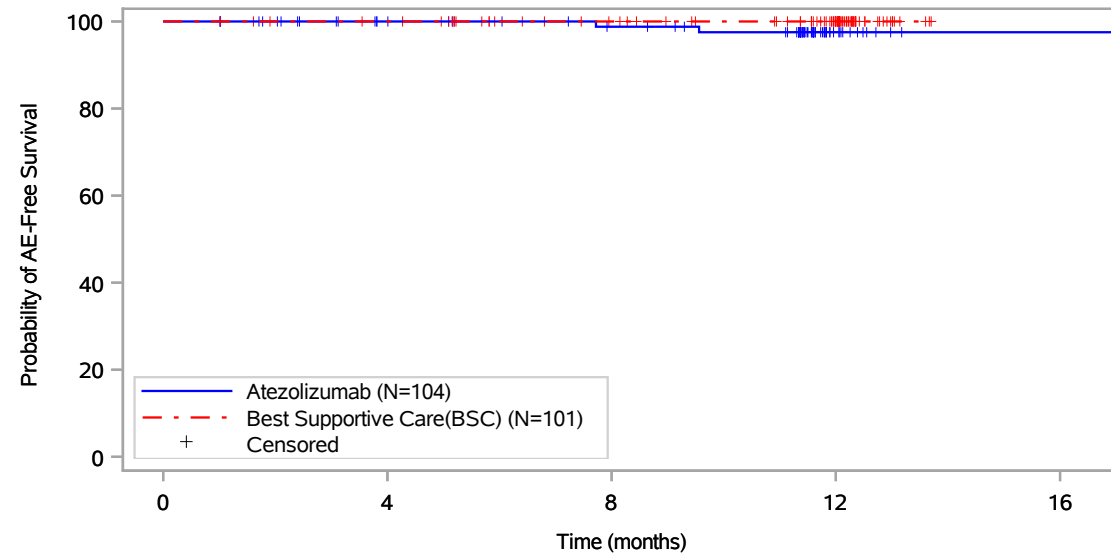
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Sinusitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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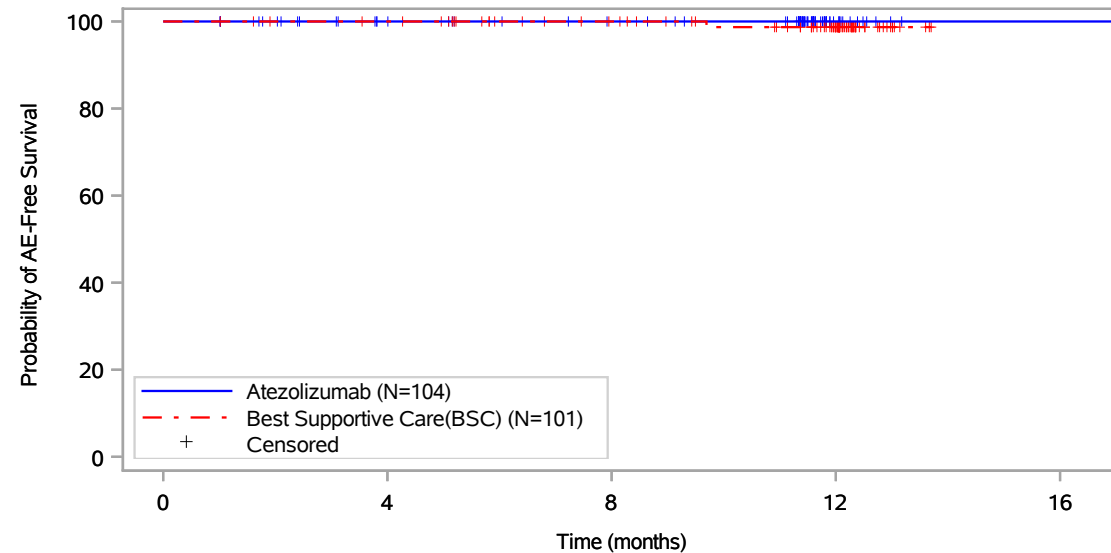
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Skin infection



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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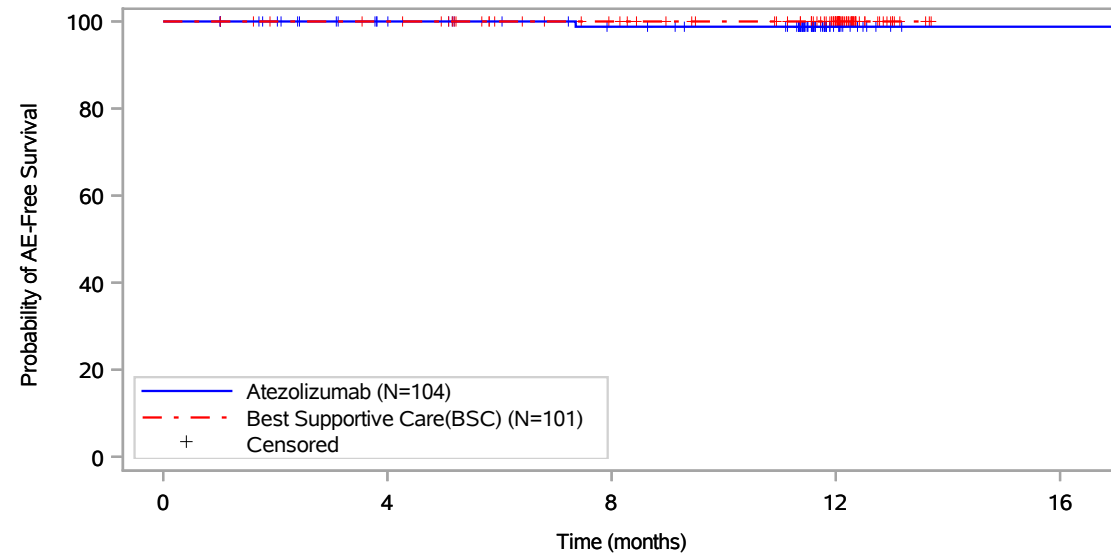
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Tinea infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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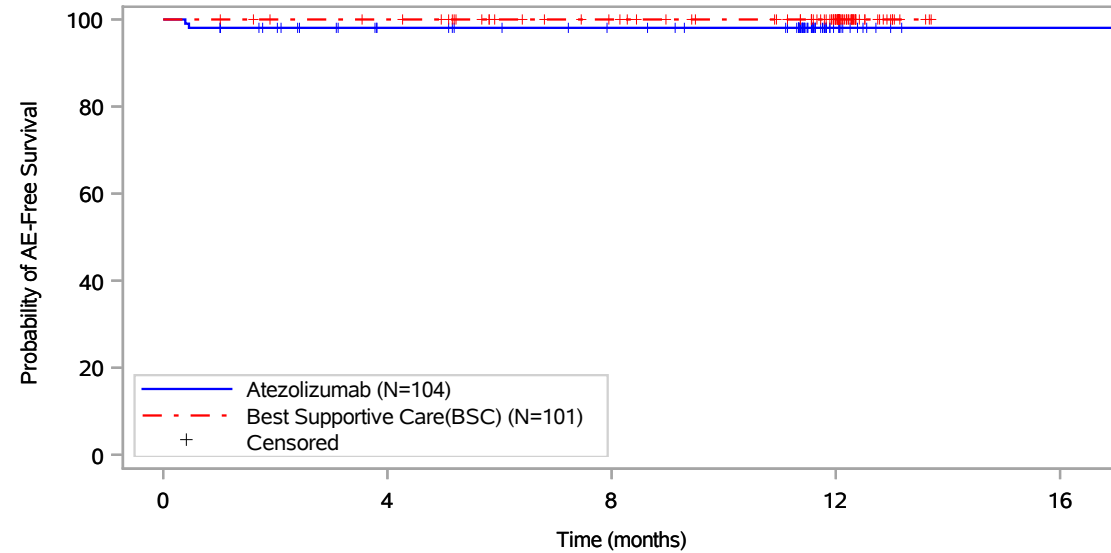
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Tonsillitis



Patients at risk					
Atezolizumab (N=104)	104	87	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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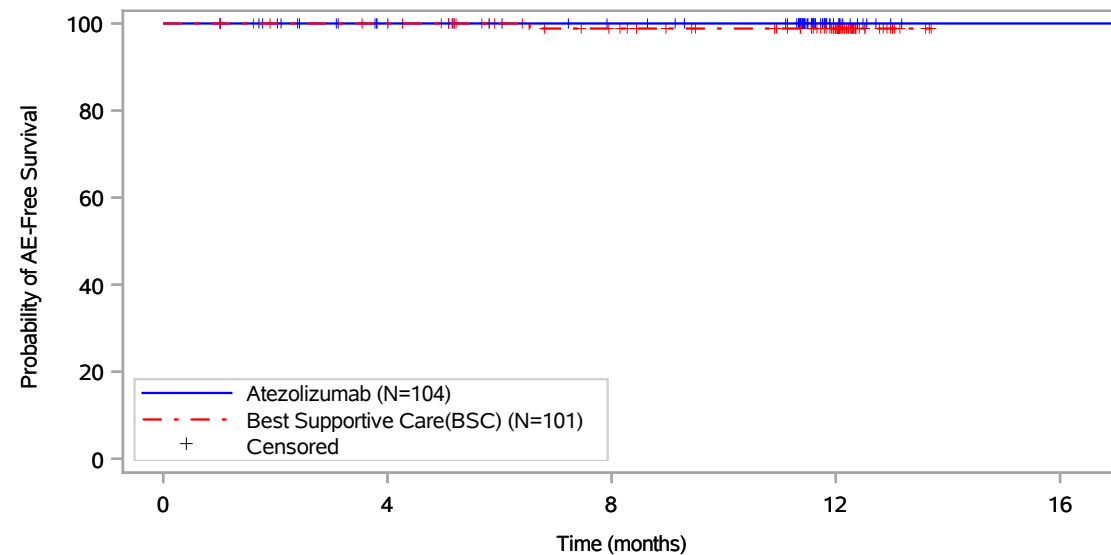
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Tooth abscess



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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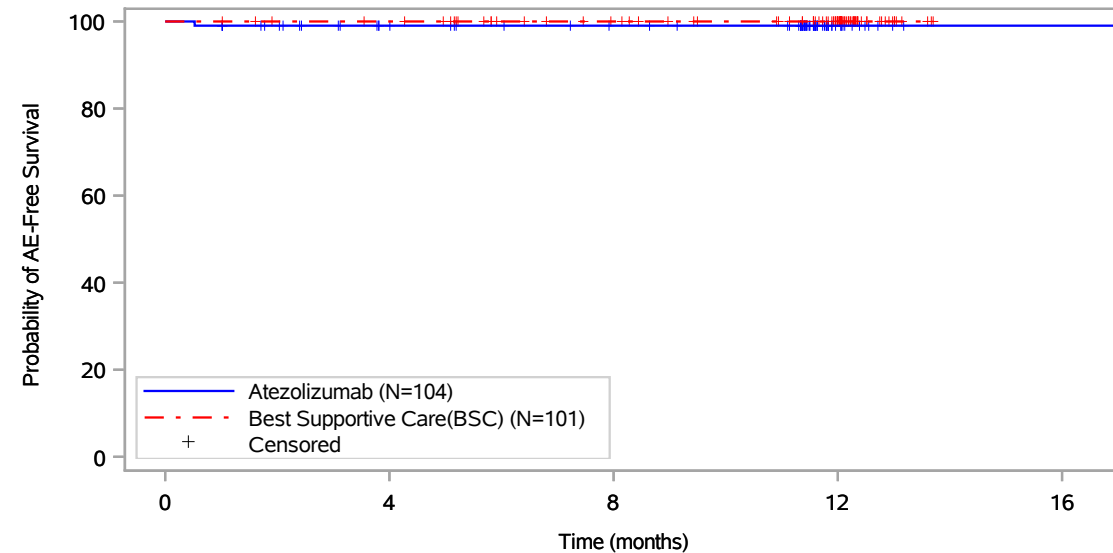
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Tooth infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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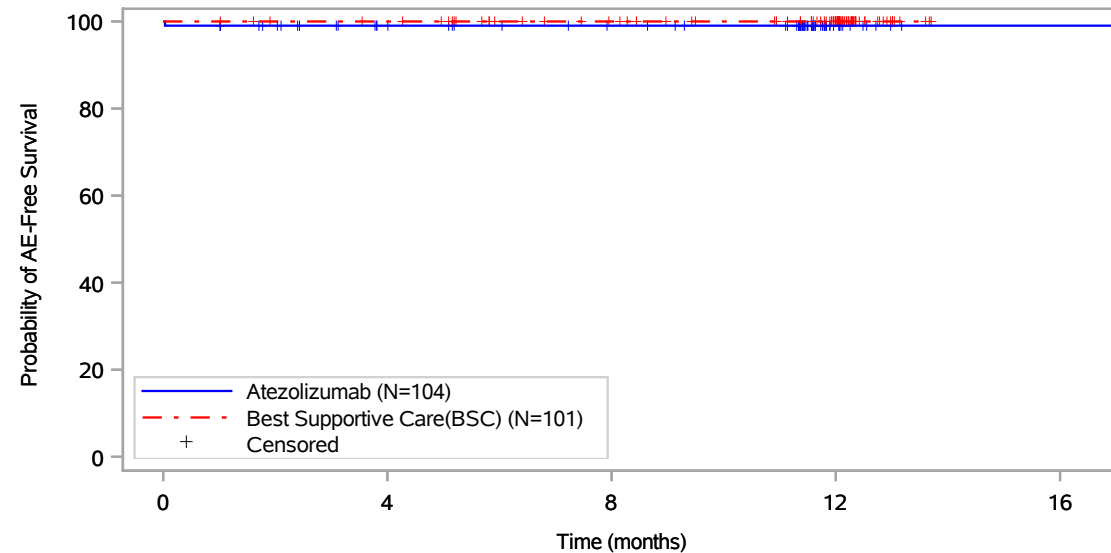
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Tracheitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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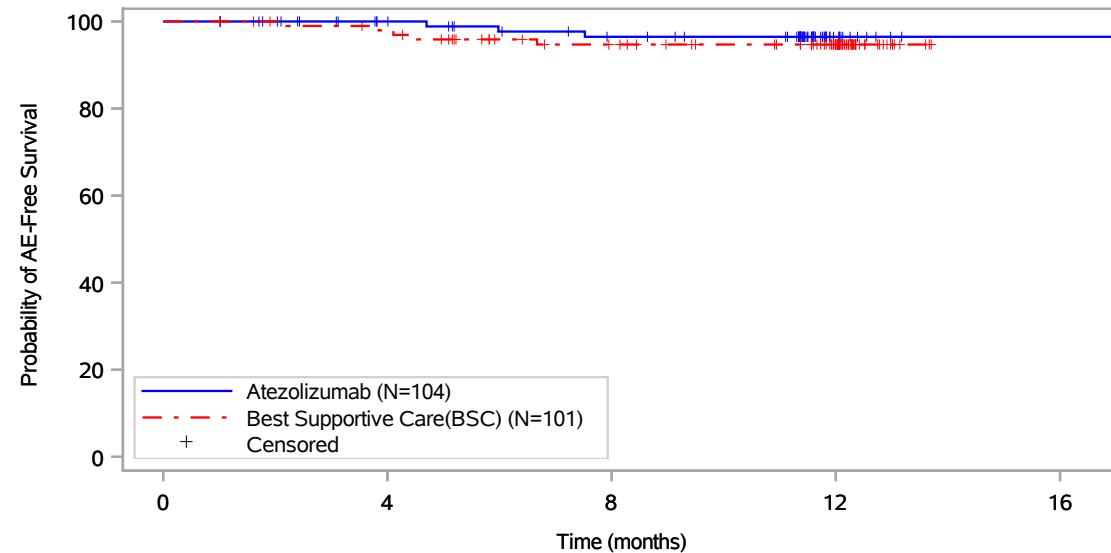
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Upper respiratory tract infection



Patients at risk					
Atezolizumab (N=104)	104	89	79	12	1
Best Supportive Care(BSC) (N=101)	101	95	79	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	100
Best Supportive Care(BSC) (N=101)	0	4	17	43	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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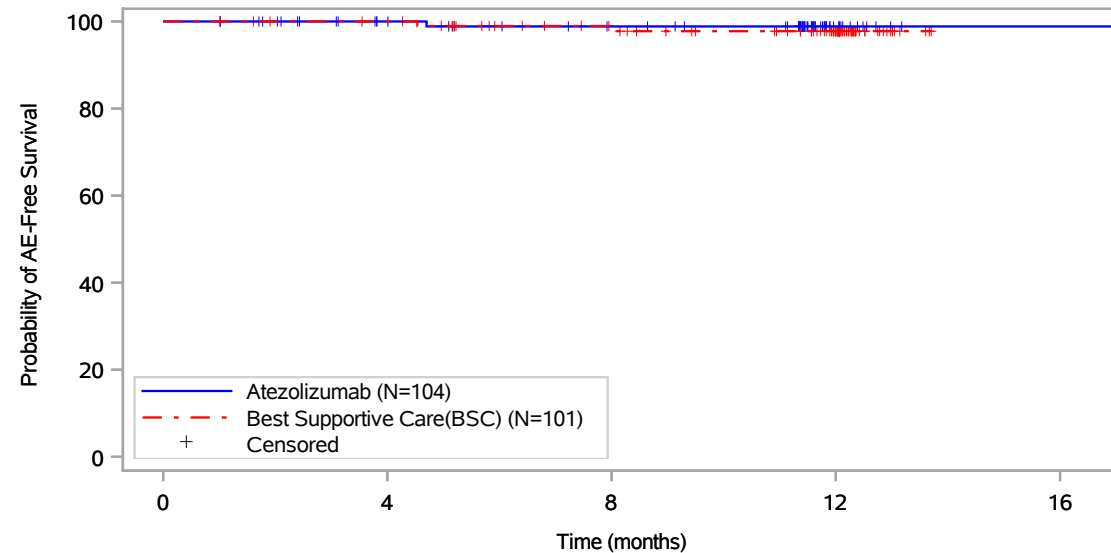
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Urinary tract infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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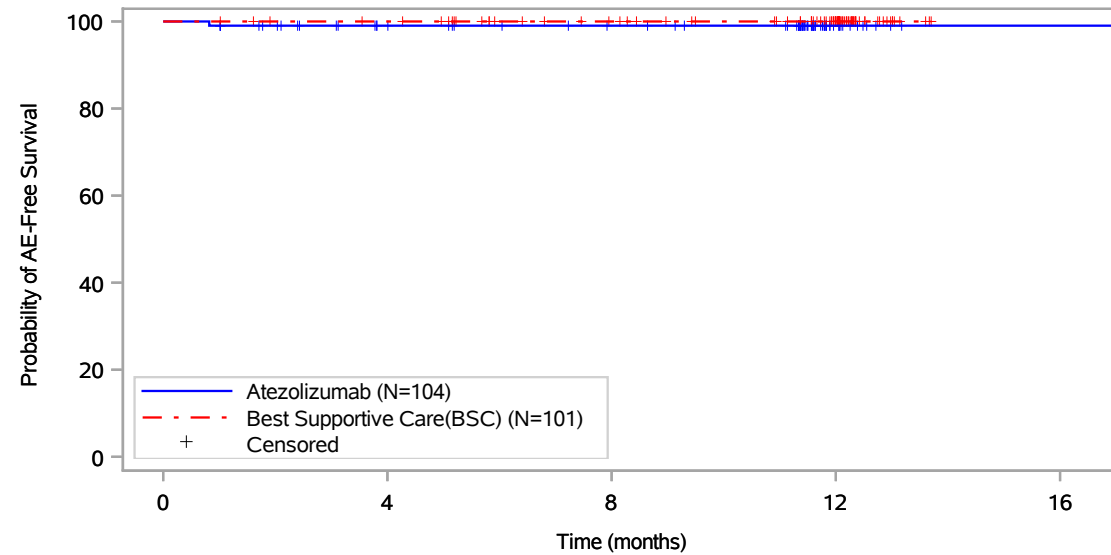
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Vaginal infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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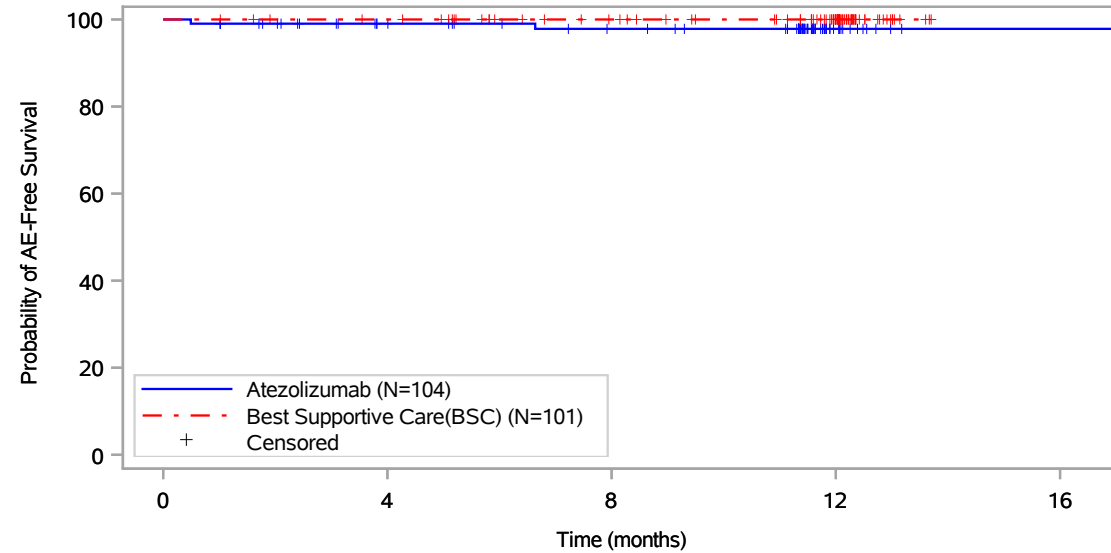
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Viral infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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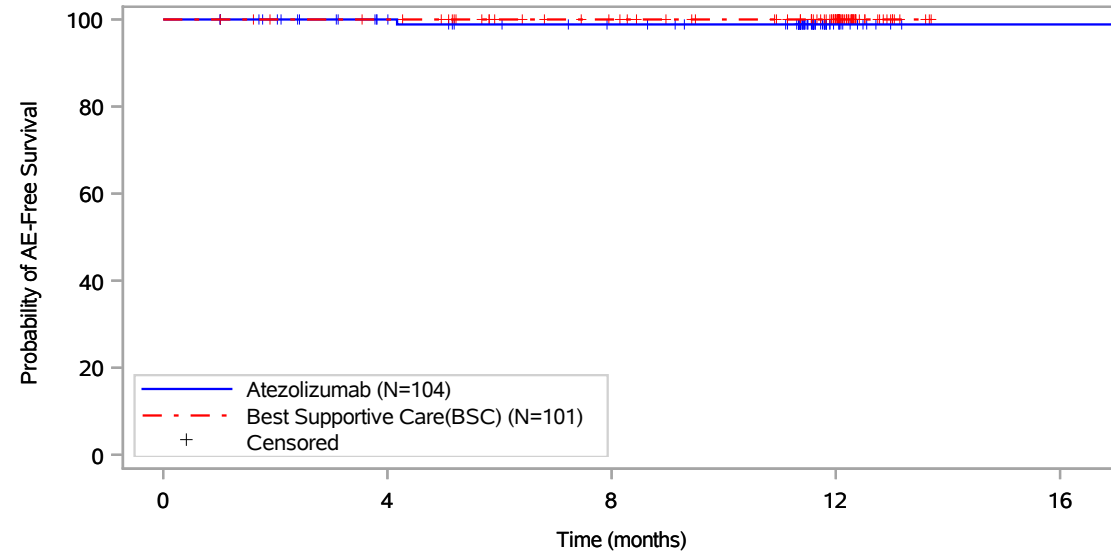
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Infections and infestations, Viral upper respiratory tract infection



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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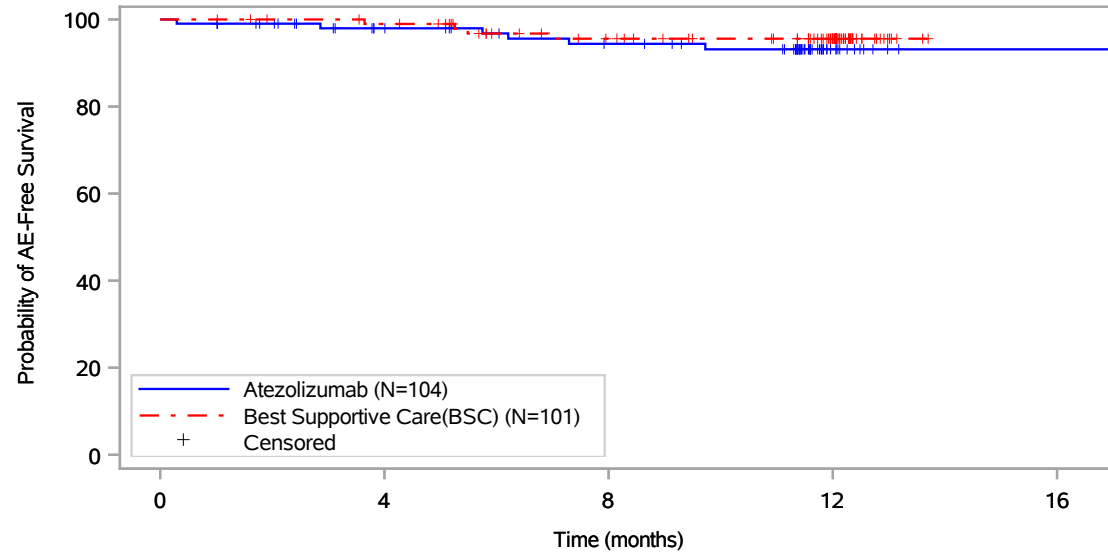
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	78	12	1
Best Supportive Care(BSC) (N=101)	101	96	79	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	86	97
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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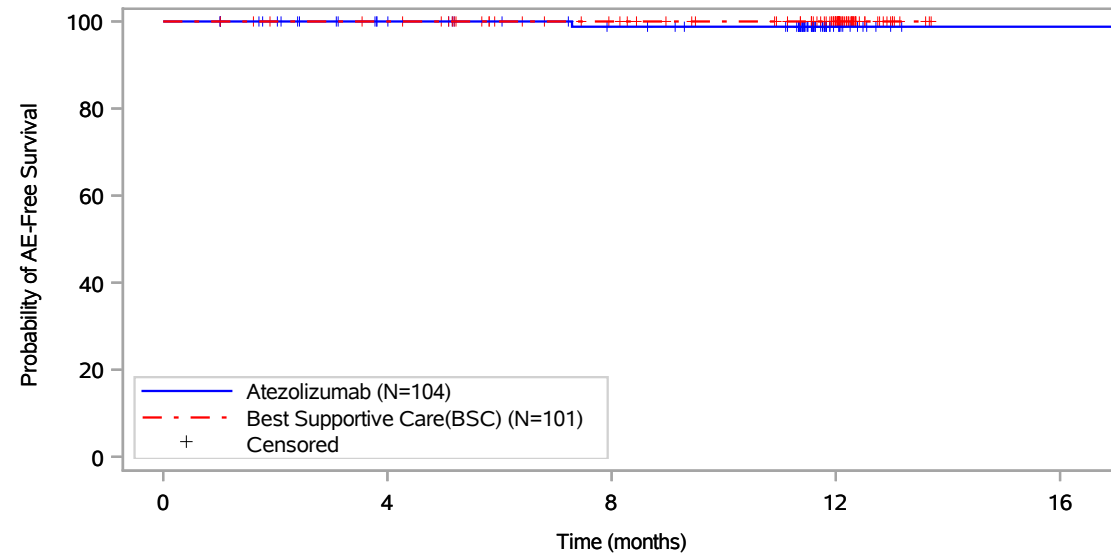
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Contusion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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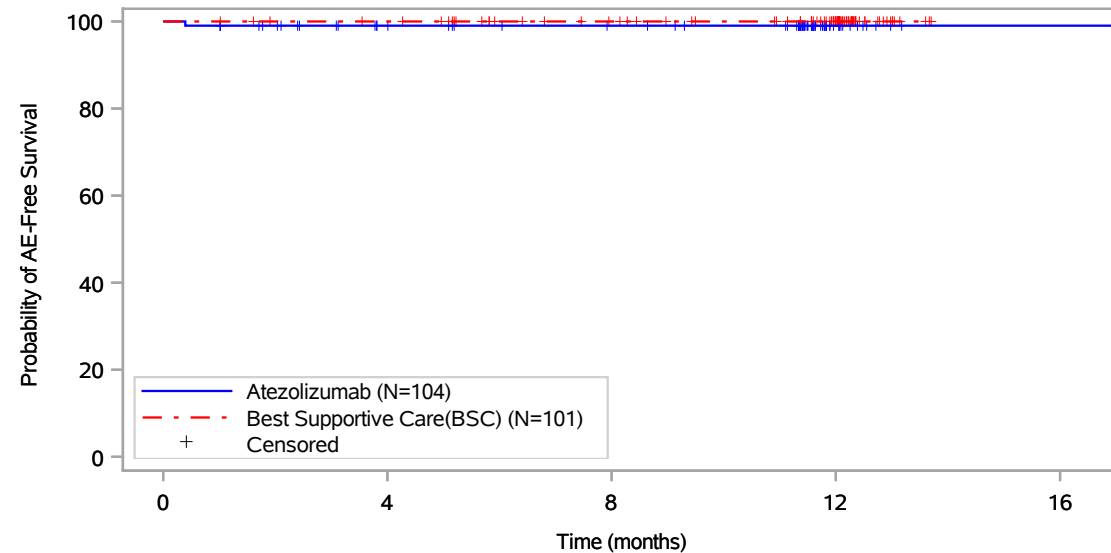
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Eye contusion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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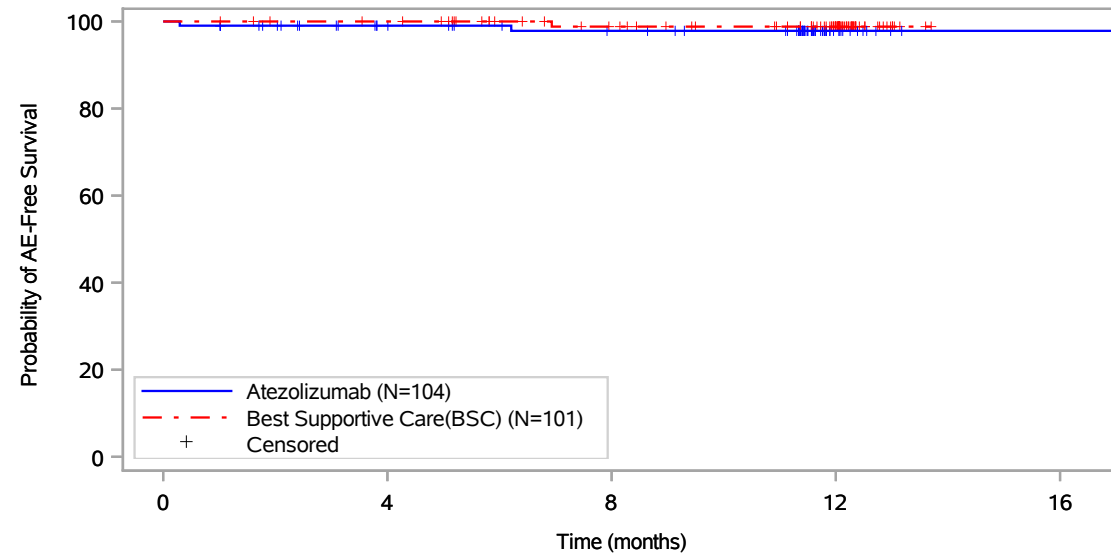
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Fall



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

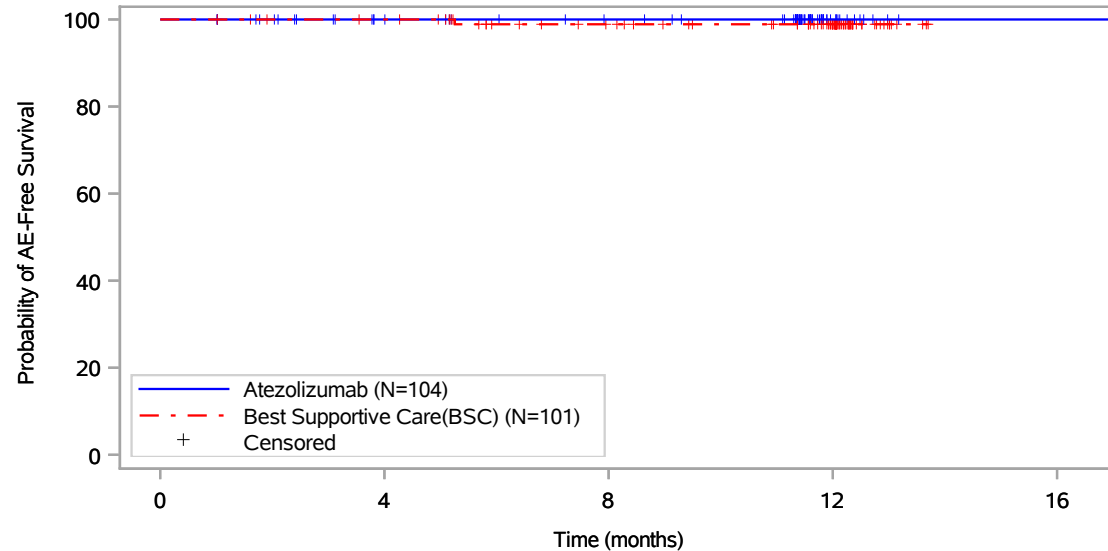
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Fracture



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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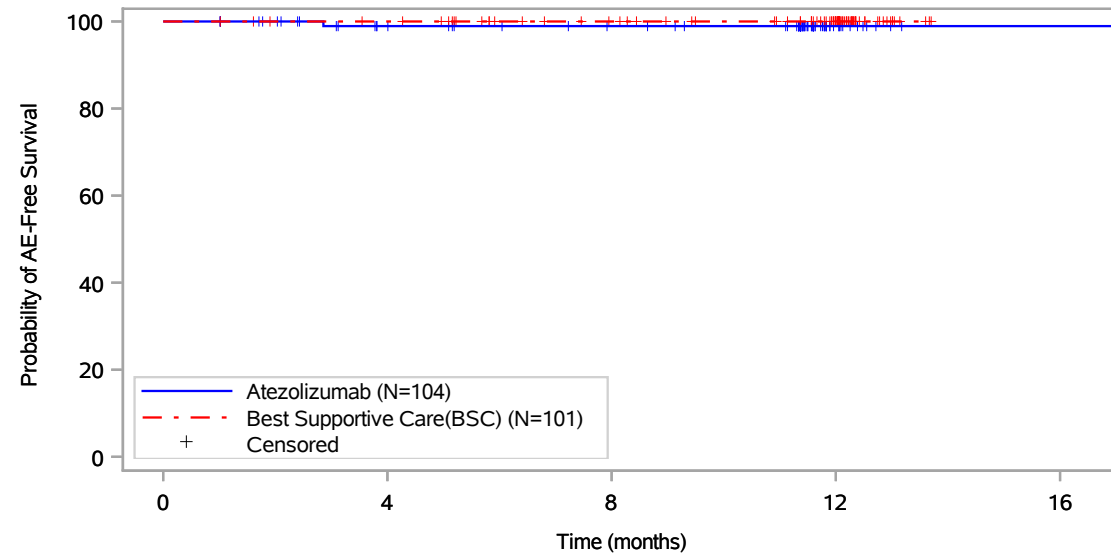
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Joint dislocation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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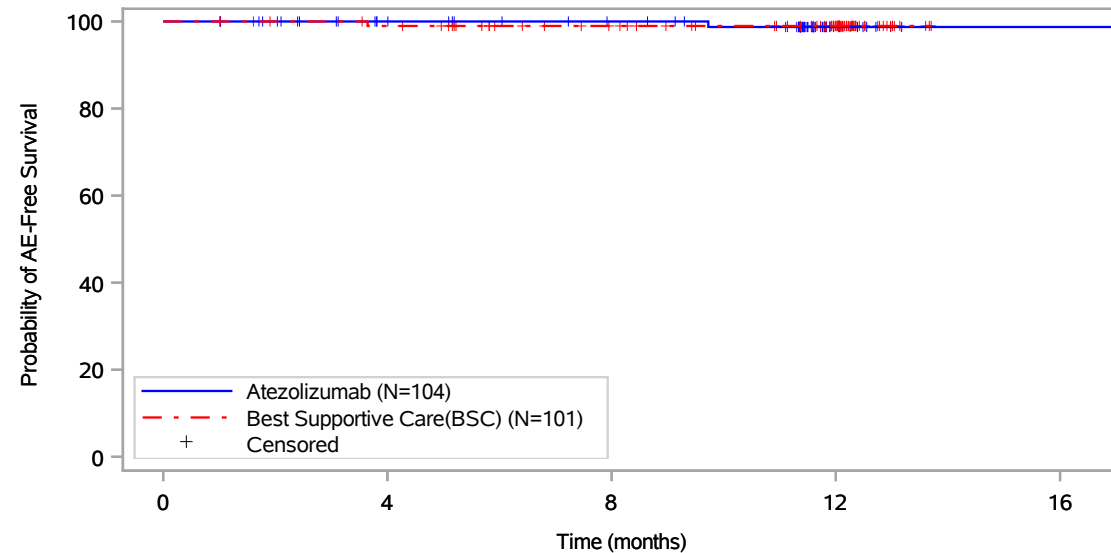
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Ligament sprain



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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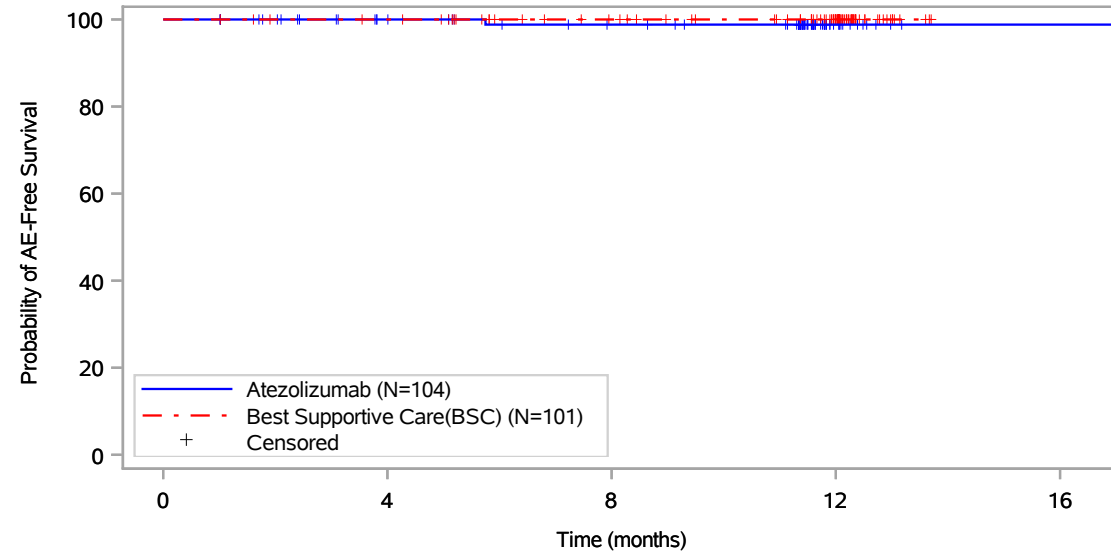
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Limb injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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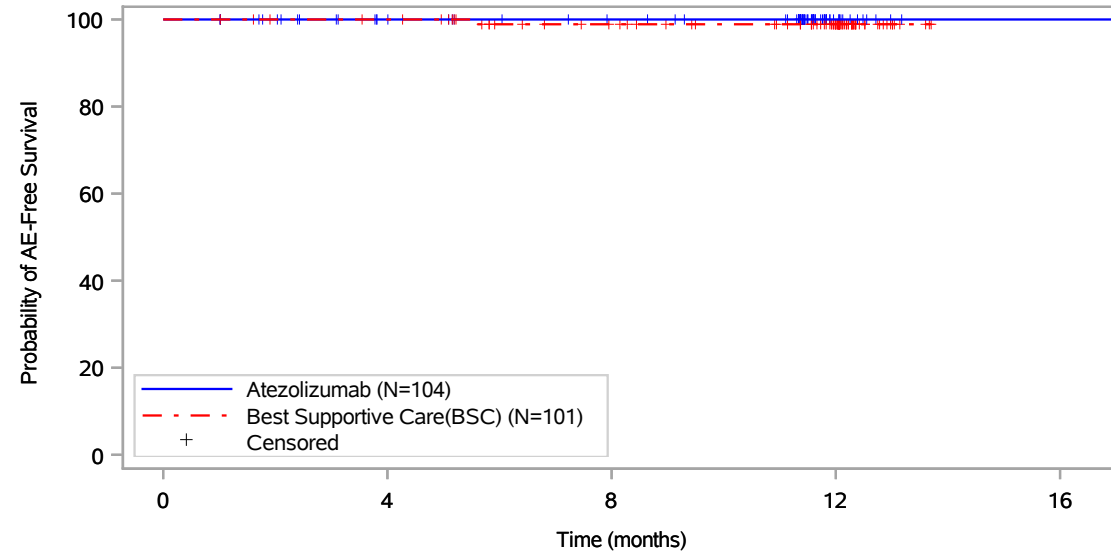
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Injury, poisoning and procedural complications, Rib fracture



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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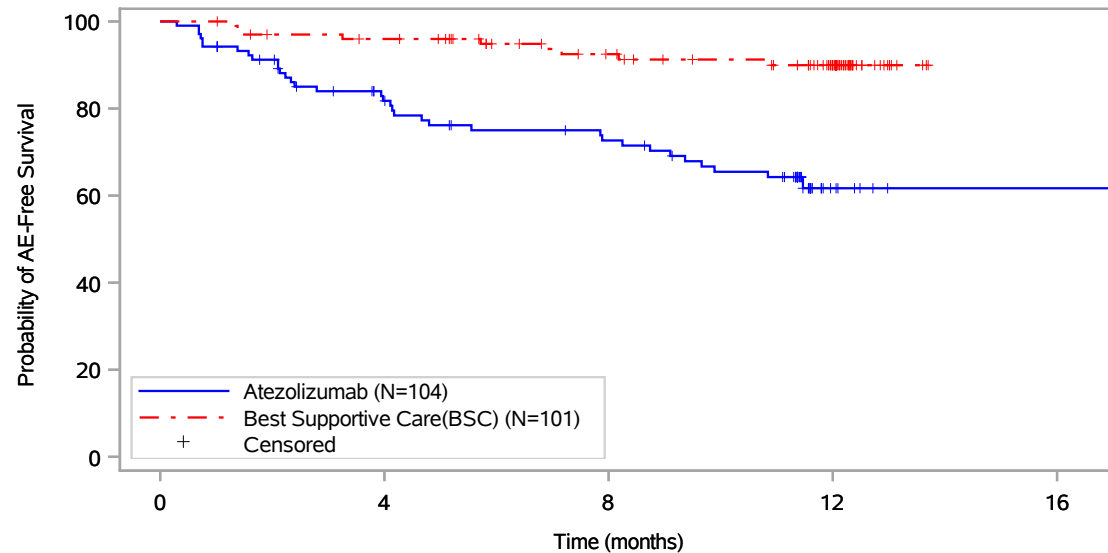
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, All



Patients at risk					
Atezolizumab (N=104)	104	74	62	7	1
Best Supportive Care(BSC) (N=101)	101	93	76	50	NE
Patients censored					
Atezolizumab (N=104)	0	12	16	63	69
Best Supportive Care(BSC) (N=101)	0	4	18	42	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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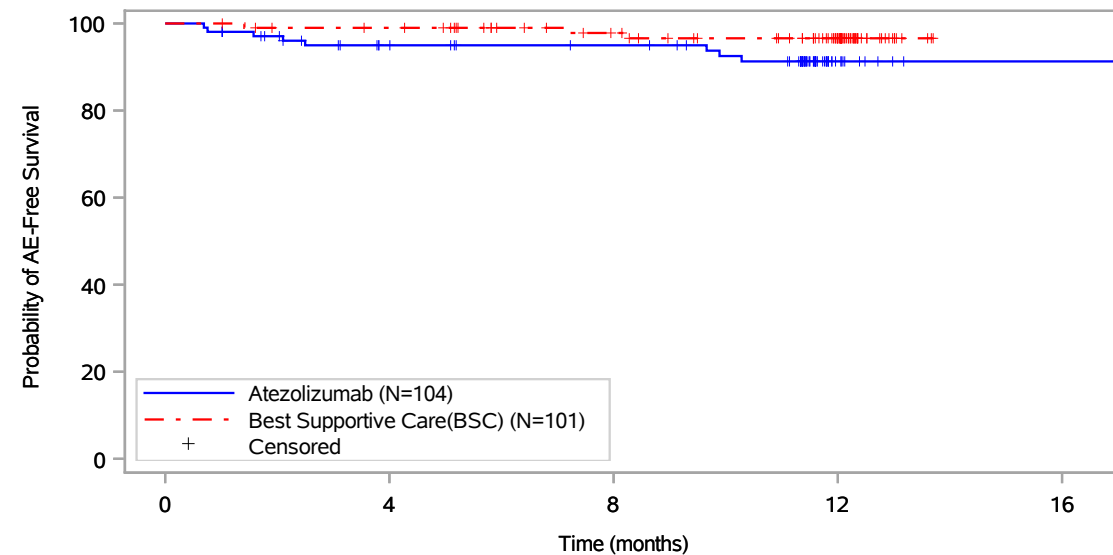
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	85	80	10	1
Best Supportive Care(BSC) (N=101)	101	96	81	52	NE
Patients censored					
Atezolizumab (N=104)	0	14	19	86	95
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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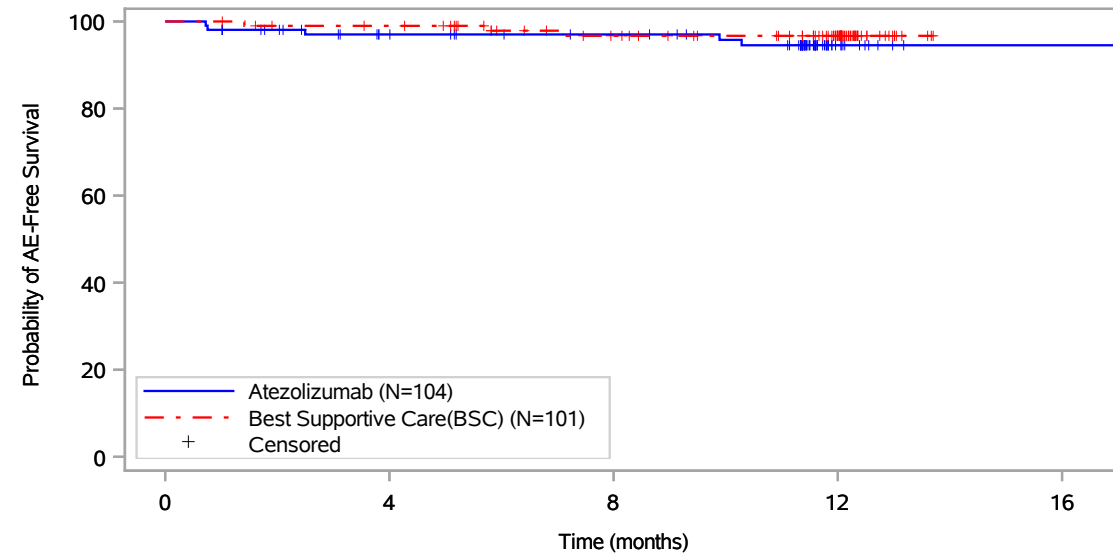
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk					
Atezolizumab (N=104)	104	87	81	11	1
Best Supportive Care(BSC) (N=101)	101	96	80	52	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	88	98
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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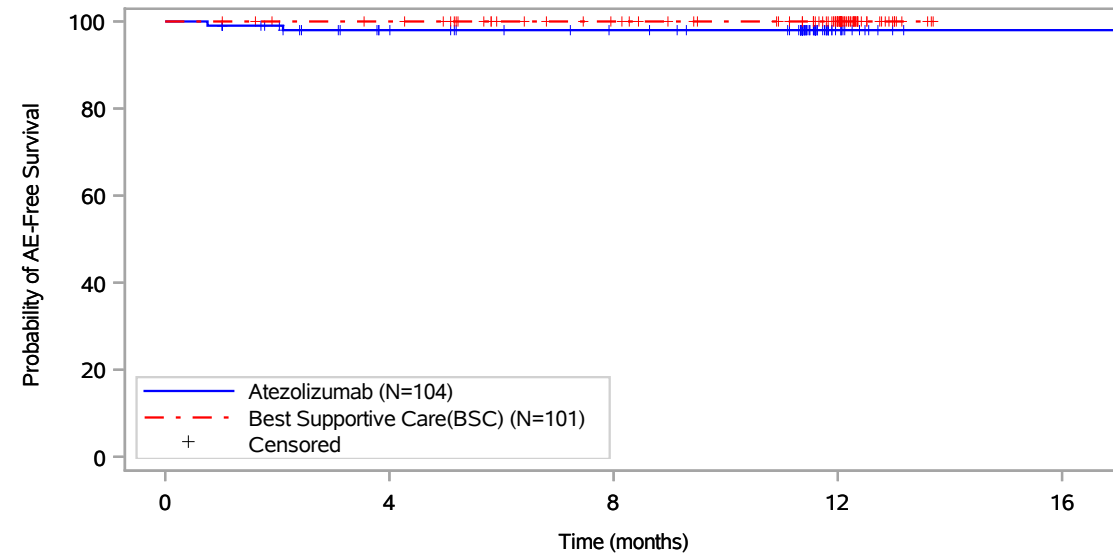
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood alkaline phosphatase increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

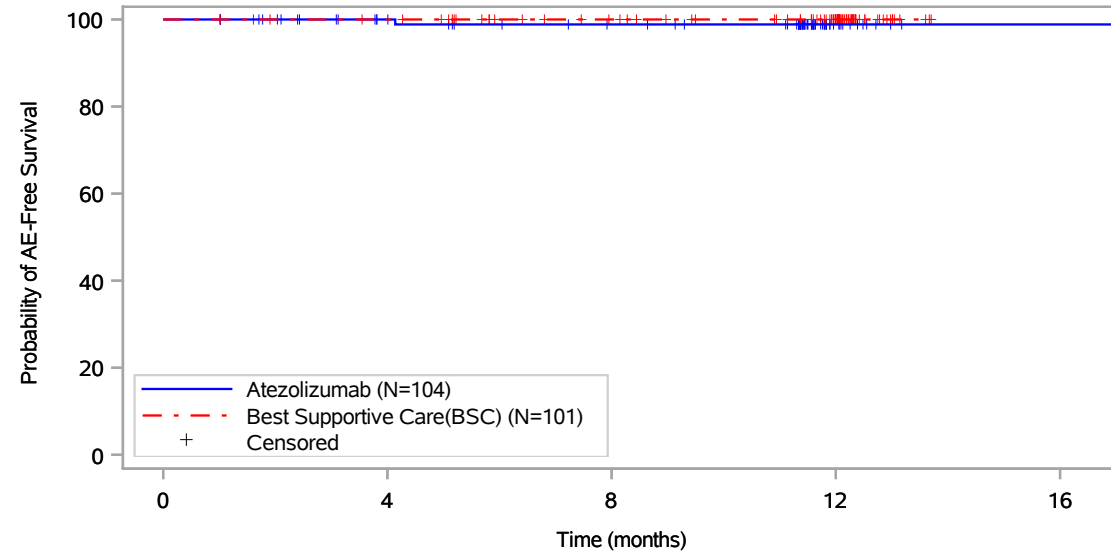
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood cholesterol increased



Patients at risk					
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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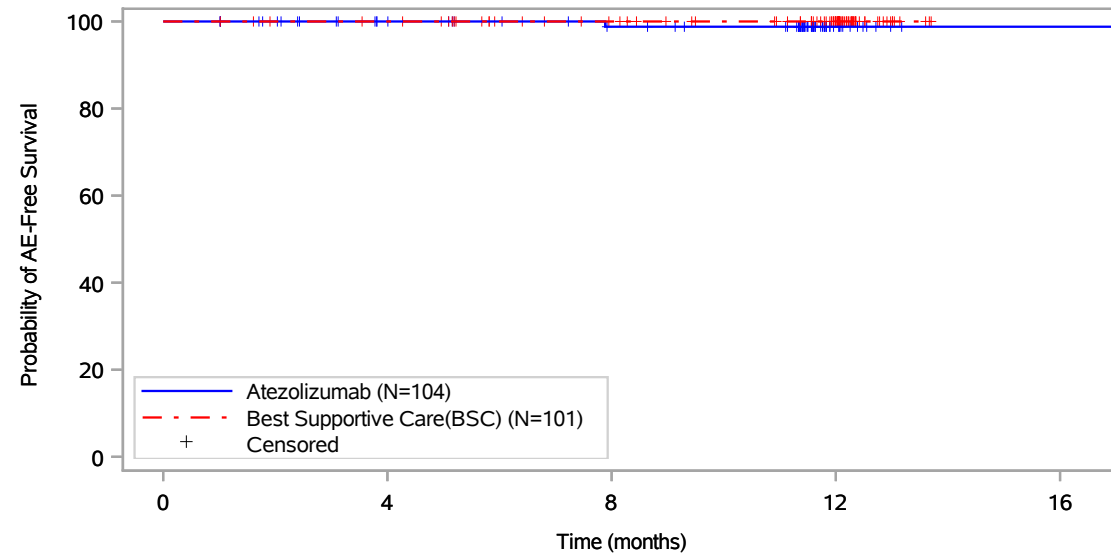
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood creatine increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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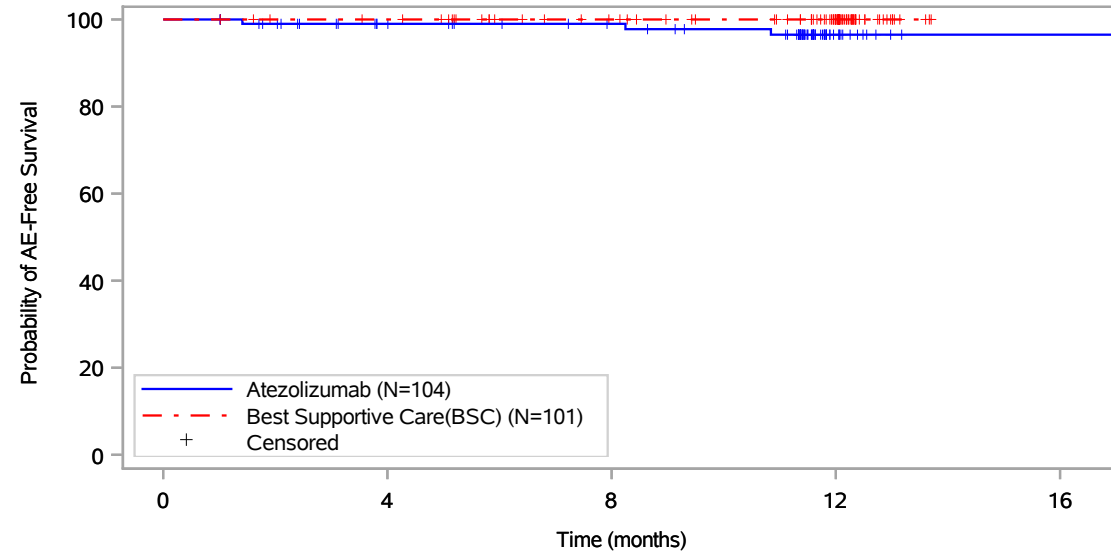
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood creatine phosphokinase increased



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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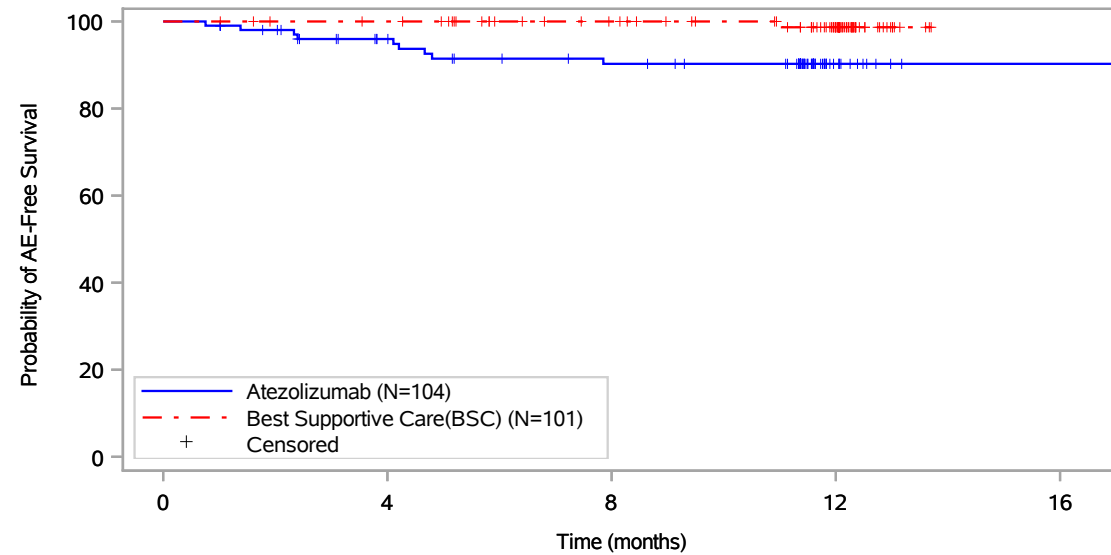
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood creatinine increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	76	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	19	83	94
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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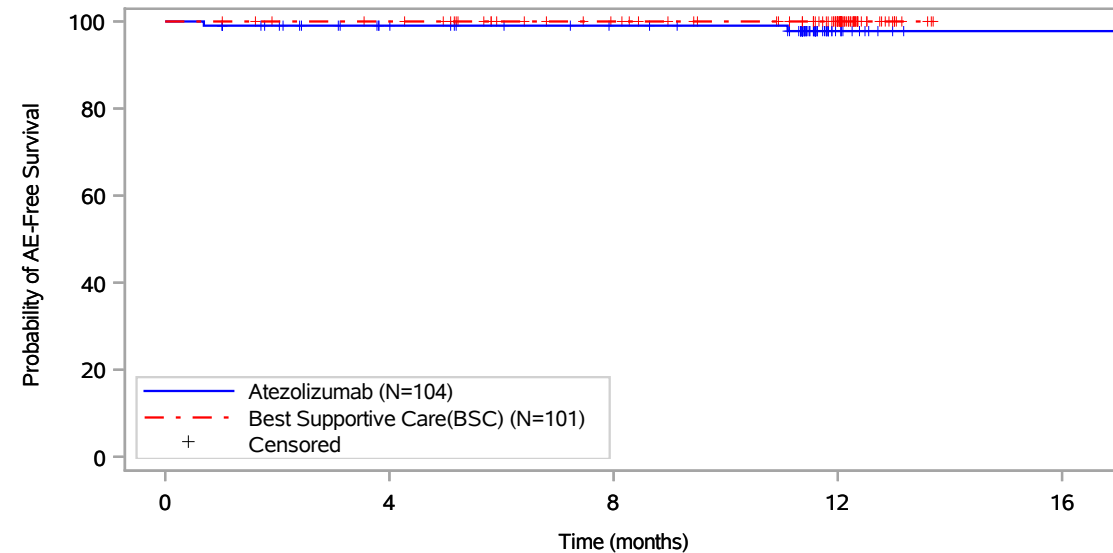
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood iron decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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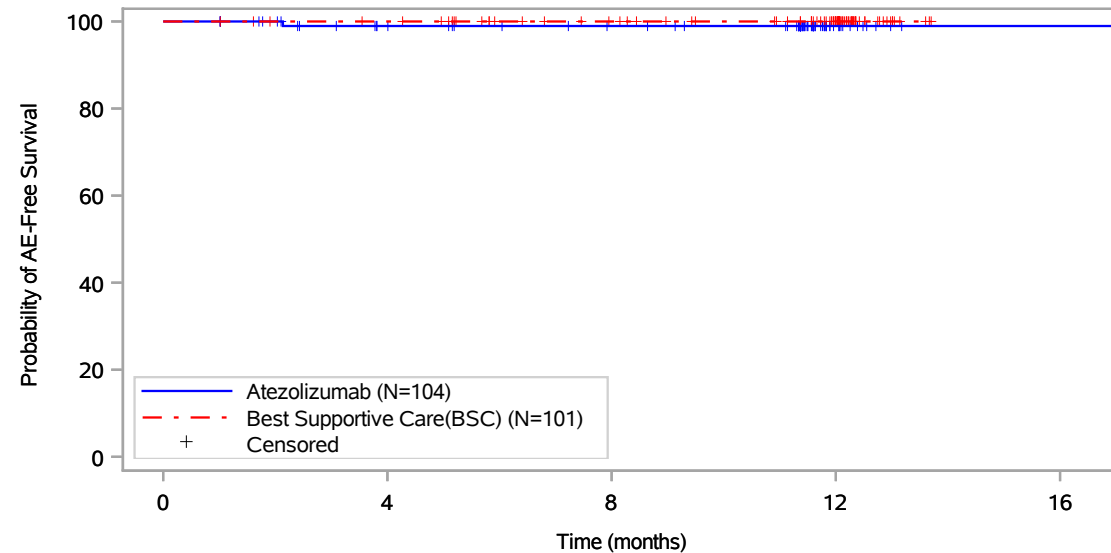
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood lactate dehydrogenase increased



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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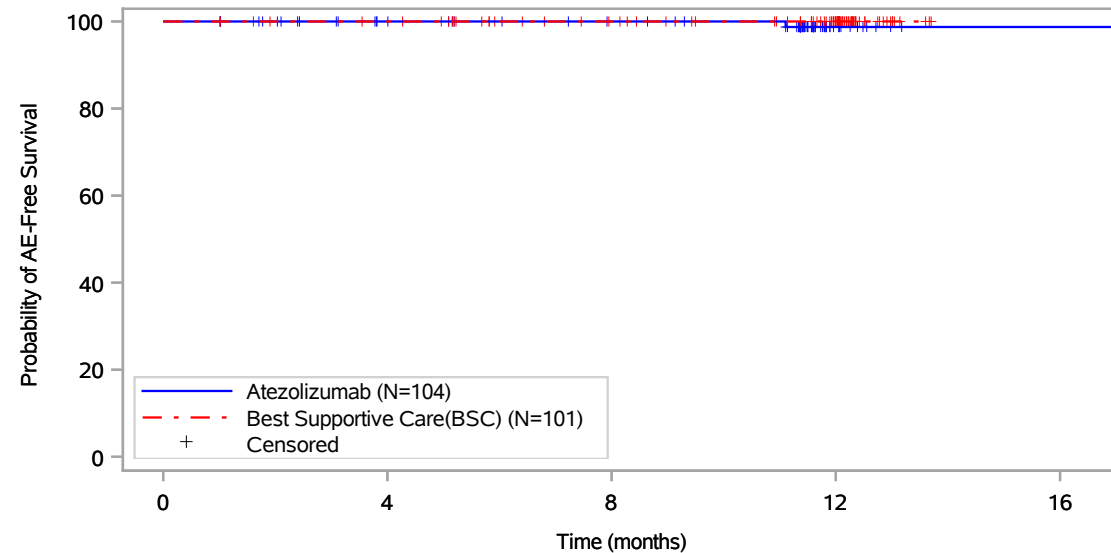
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood magnesium decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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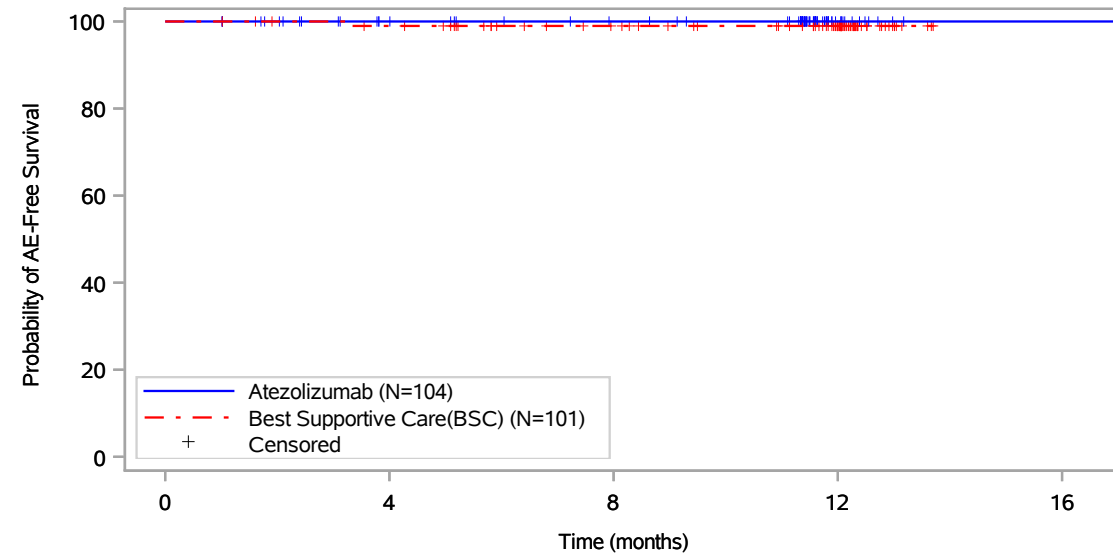
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood pressure increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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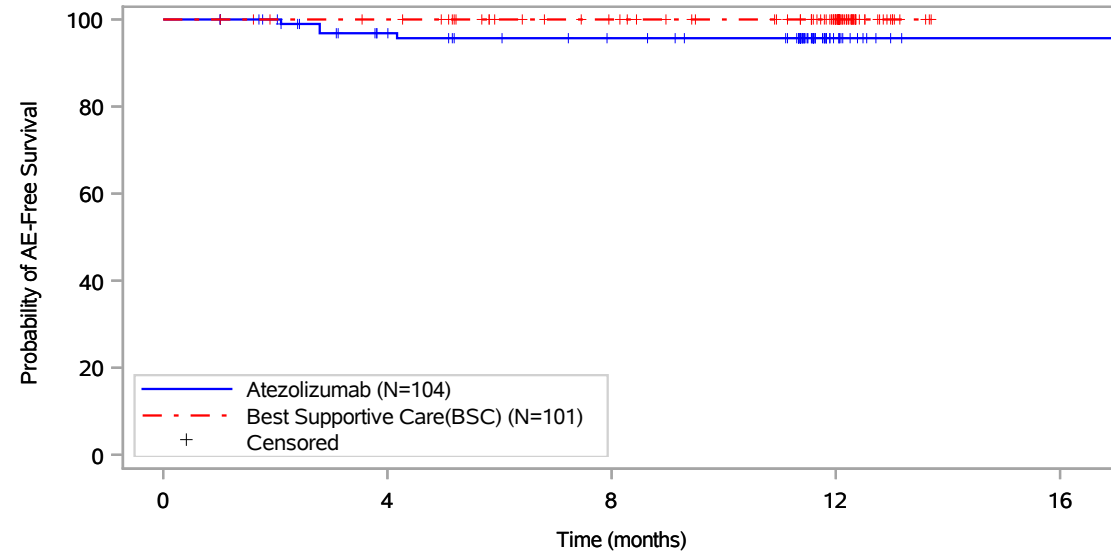
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood thyroid stimulating hormone decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	78	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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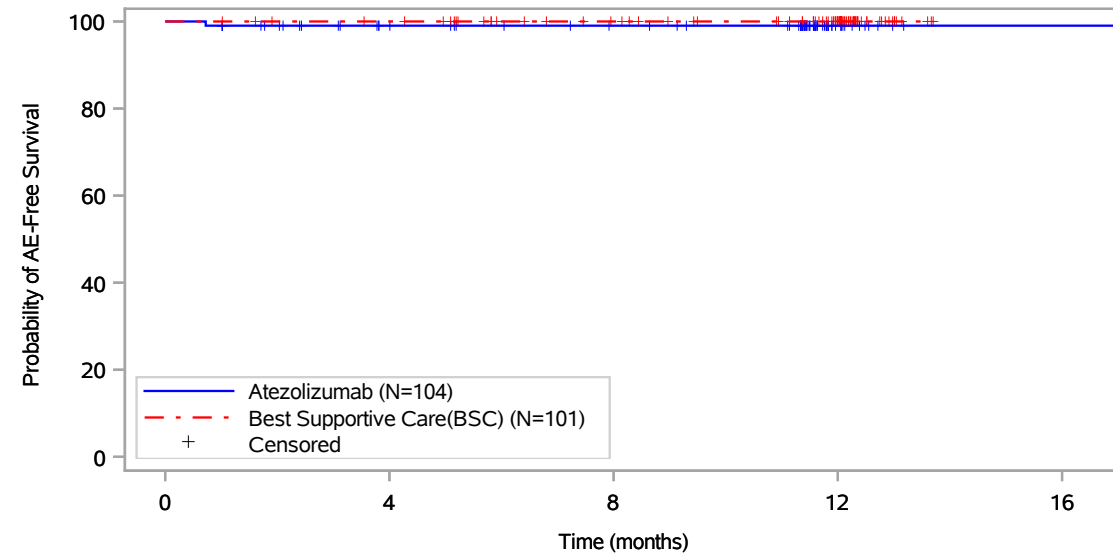
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood triglycerides increased



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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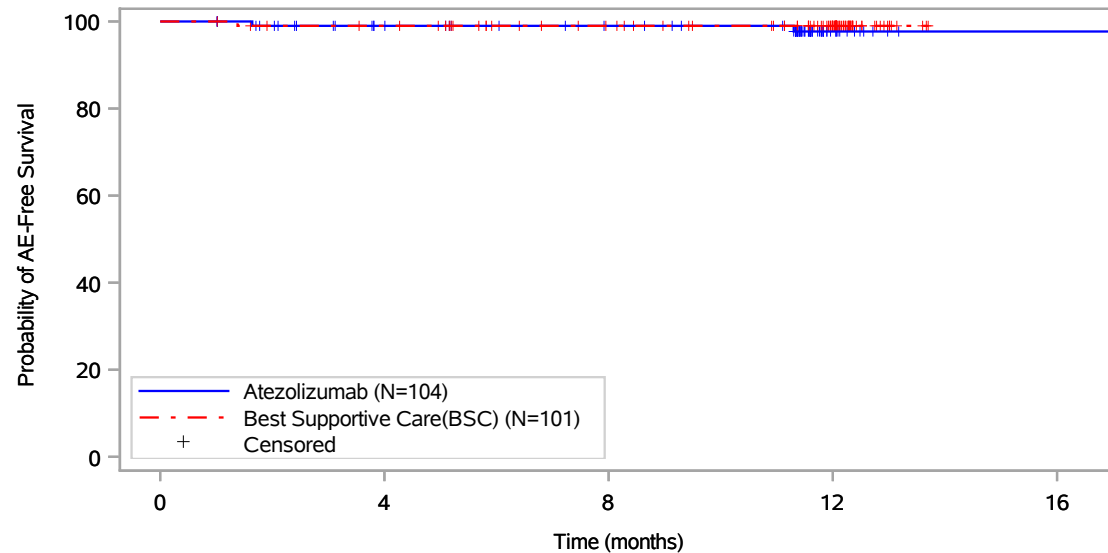
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood uric acid increased



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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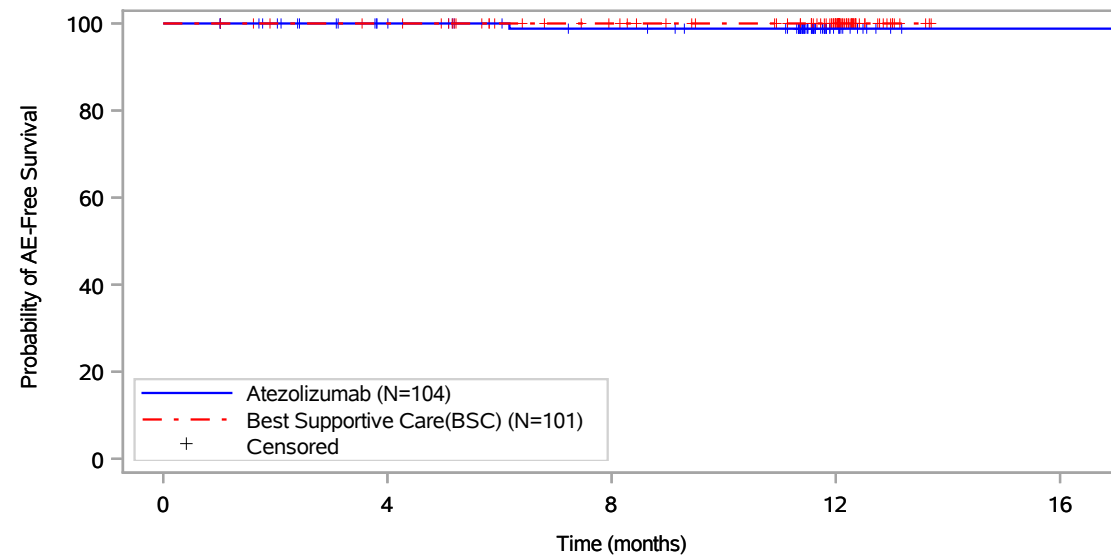
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Creatinine renal clearance decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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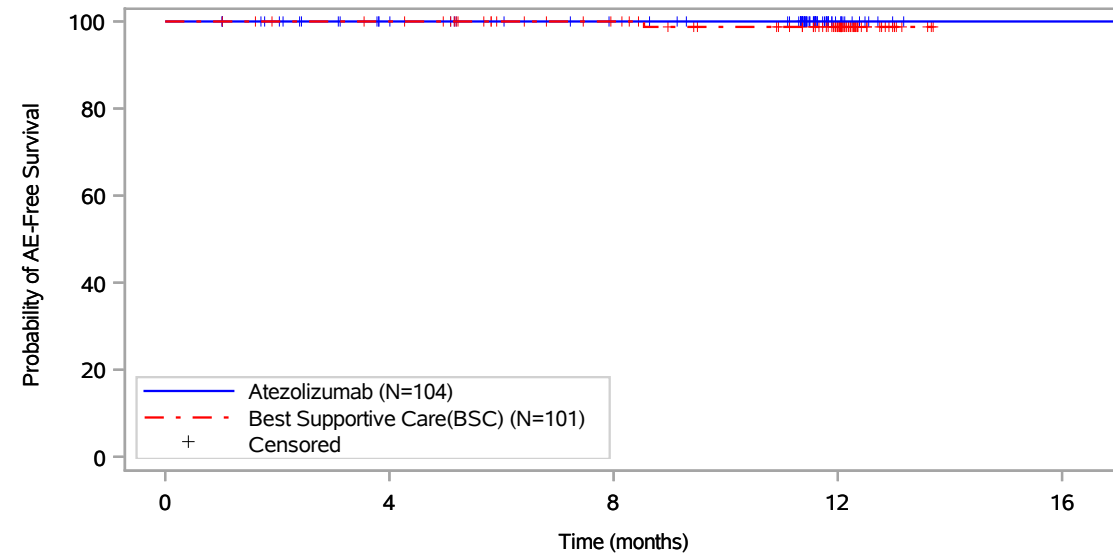
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Gamma-glutamyltransferase increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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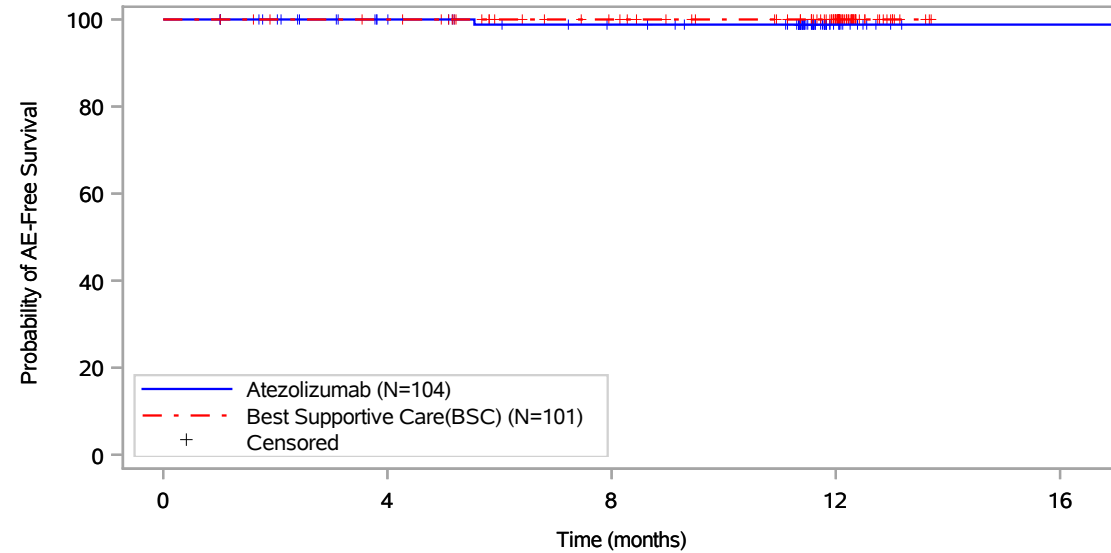
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Gastric pH decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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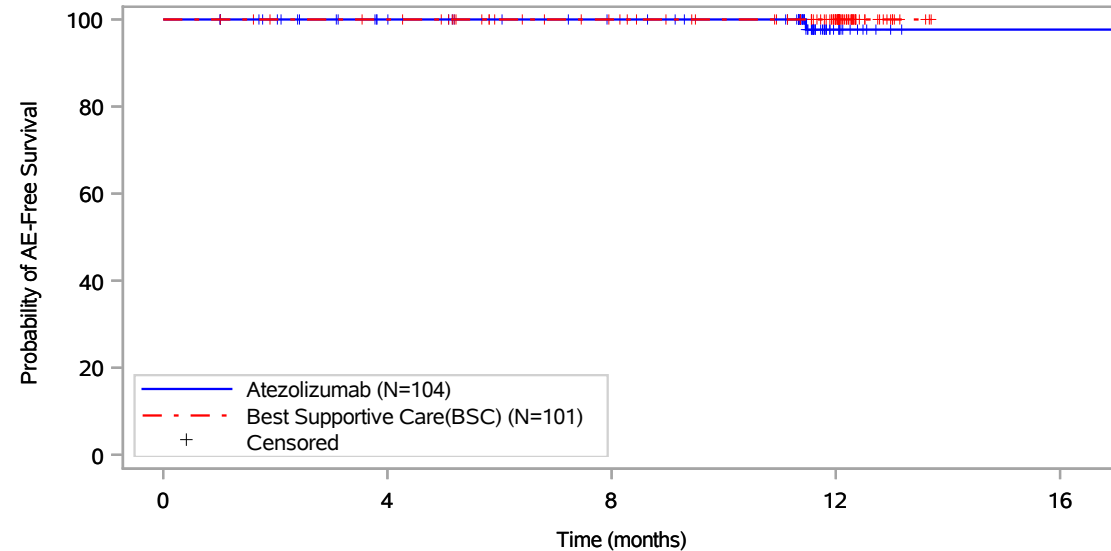
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, International normalised ratio increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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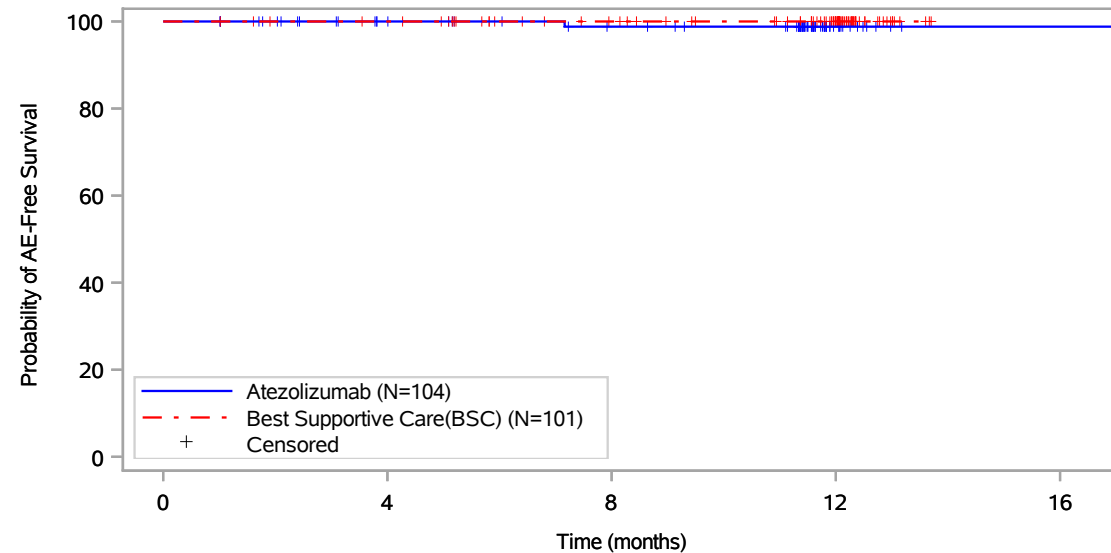
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Liver function test increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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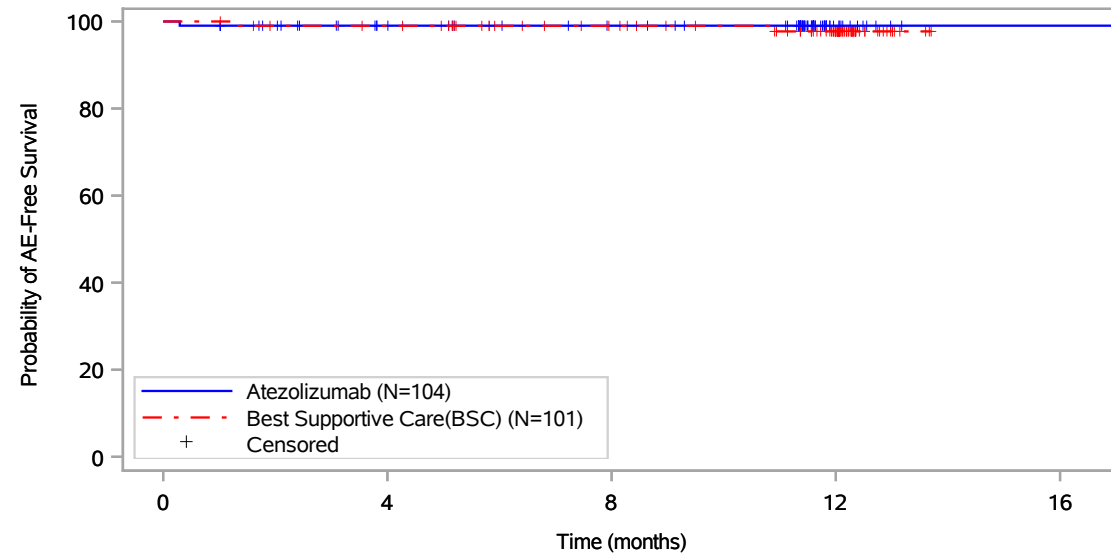
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Neutrophil count decreased



Patients at risk					
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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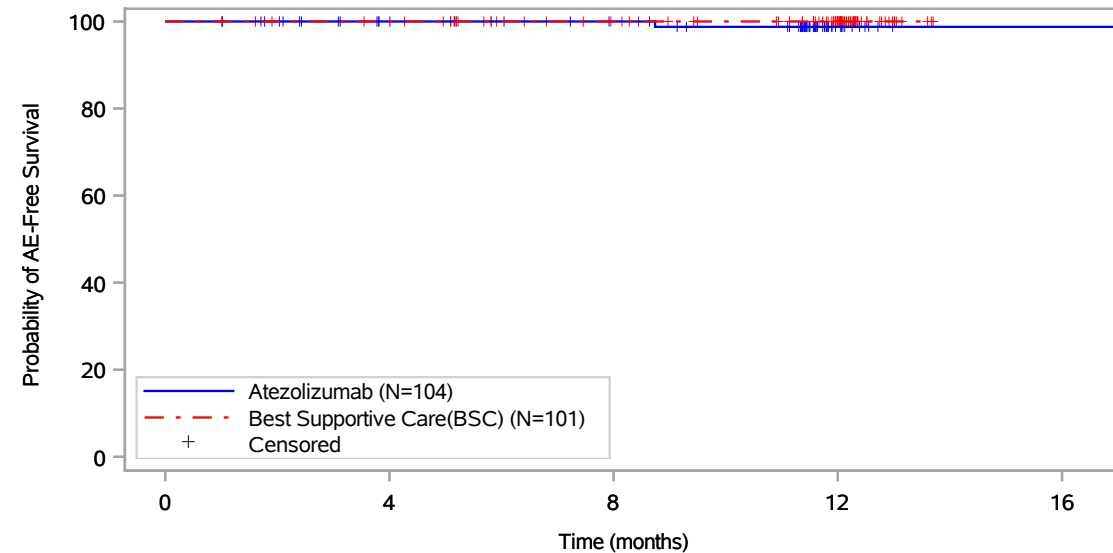
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Oxygen saturation decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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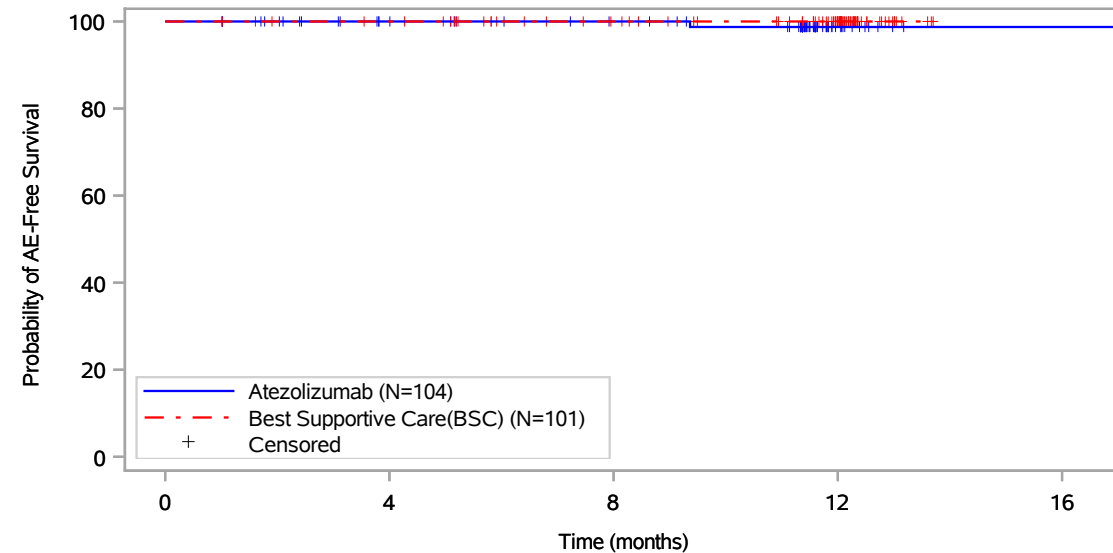
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Transaminases increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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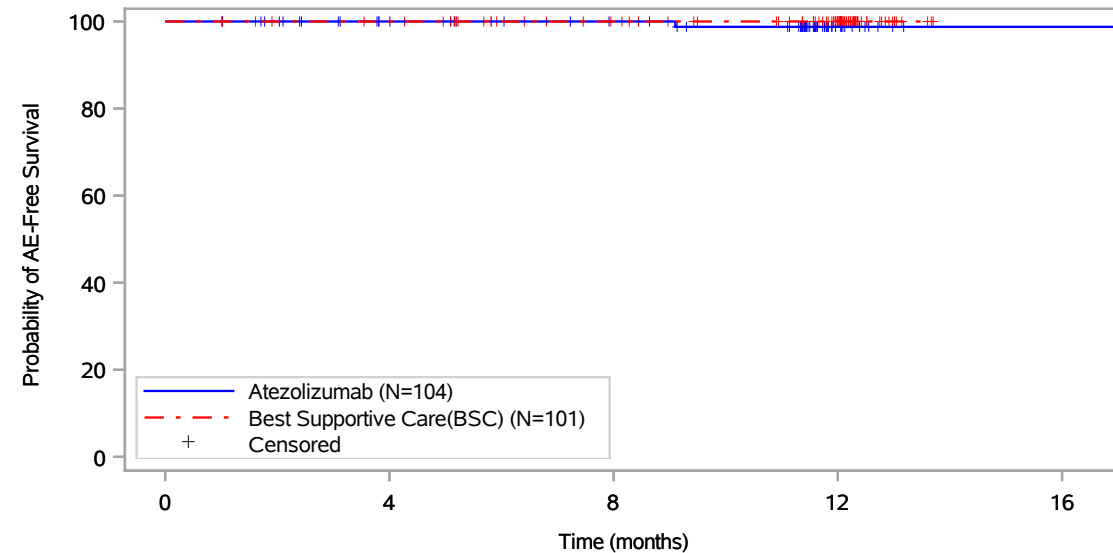
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Urine bilirubin increased



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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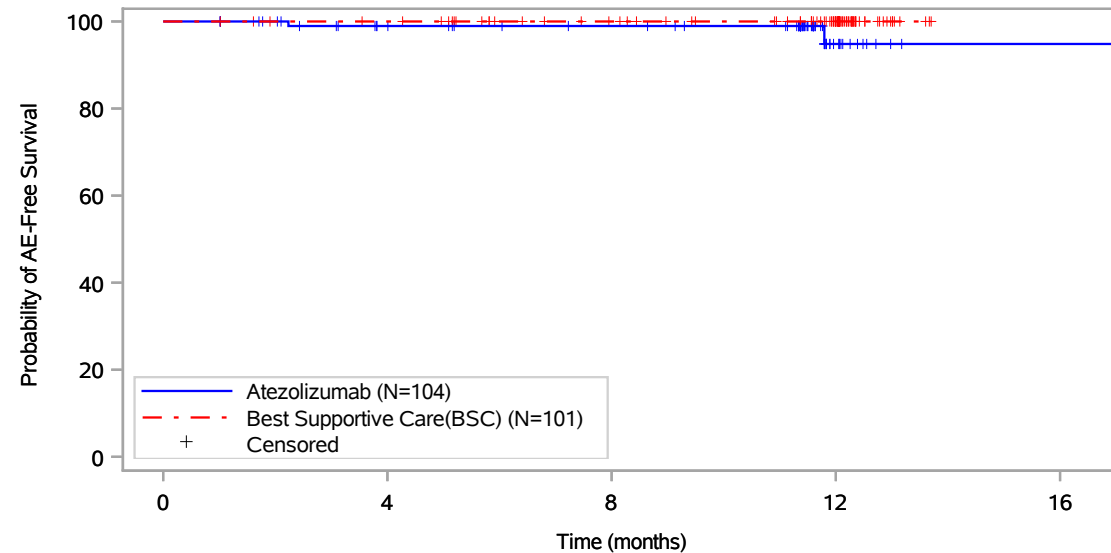
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Weight decreased



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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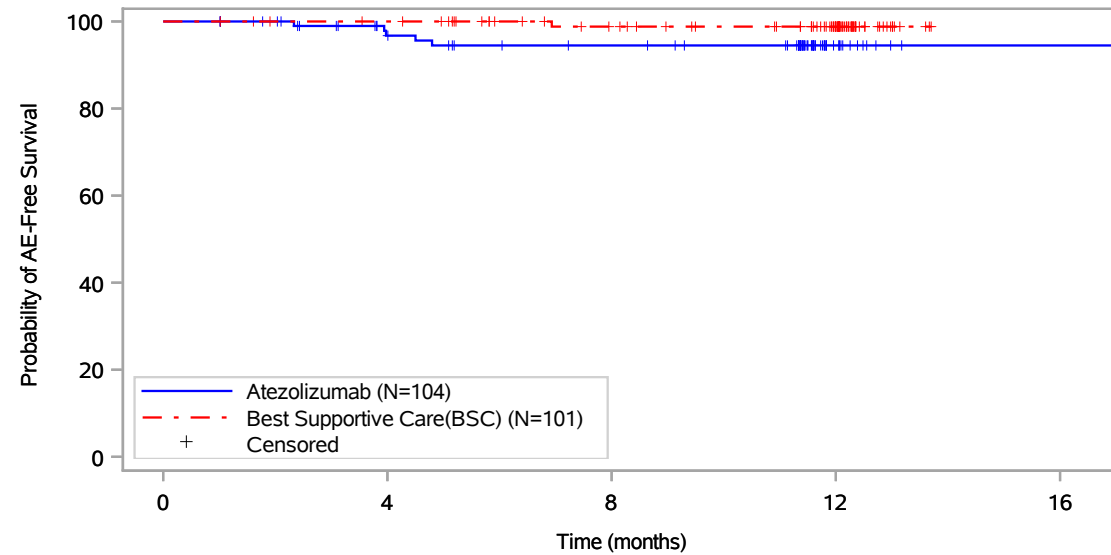
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Weight increased



Patients at risk					
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	86	98
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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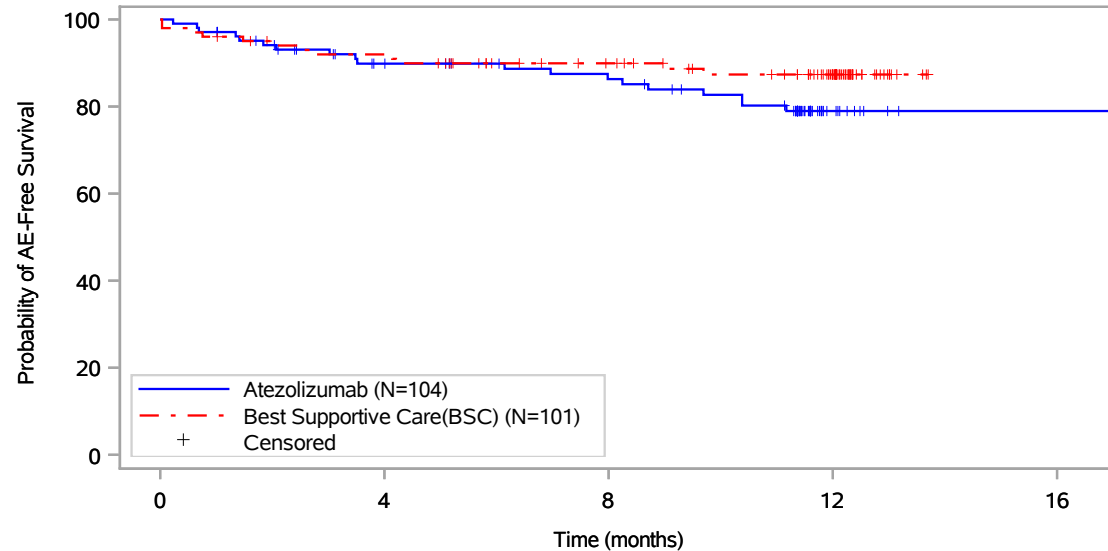
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	81	73	10	1
Best Supportive Care(BSC) (N=101)	101	90	75	48	NE
Patients censored					
Atezolizumab (N=104)	0	13	18	75	84
Best Supportive Care(BSC) (N=101)	0	3	16	41	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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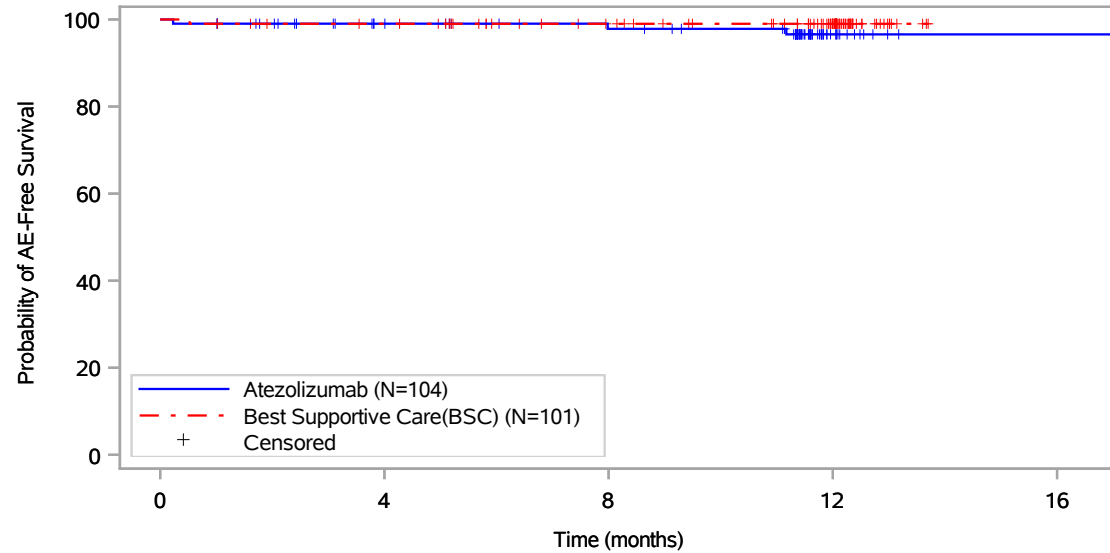
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Decreased appetite



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	20	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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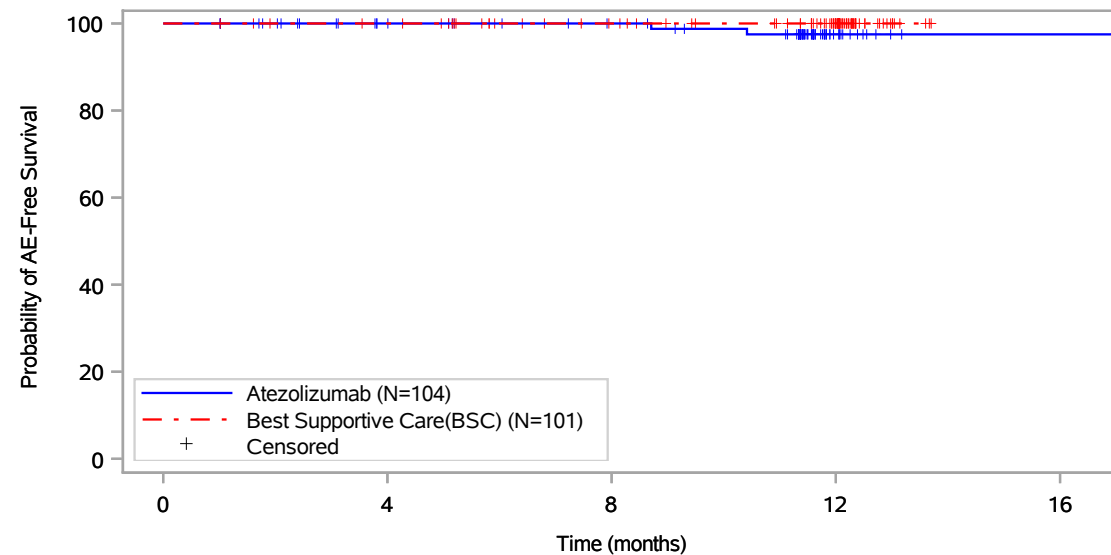
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Dehydration



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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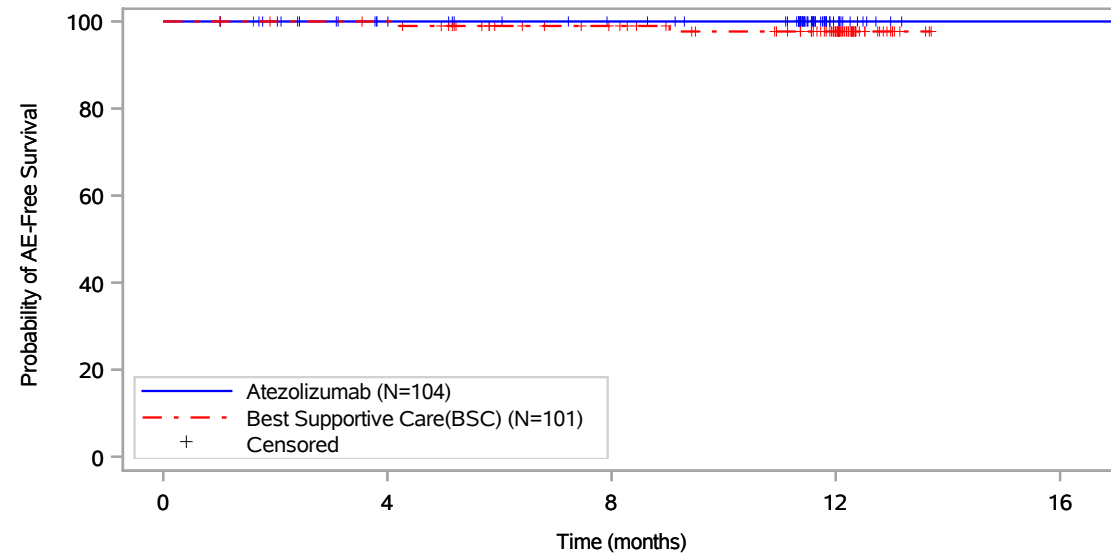
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypercholesterolaemia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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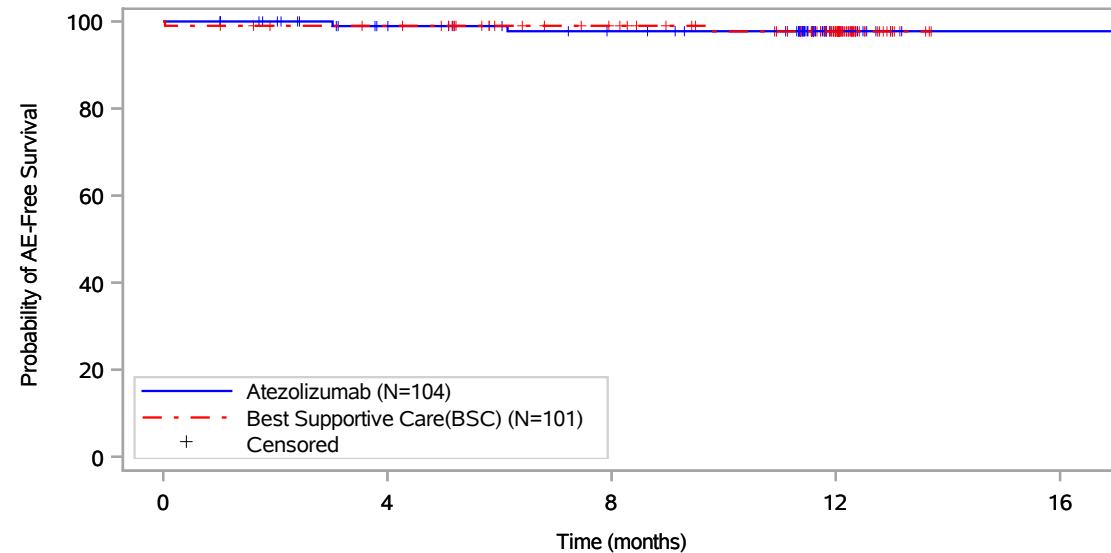
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hyperglycaemia



Patients at risk					
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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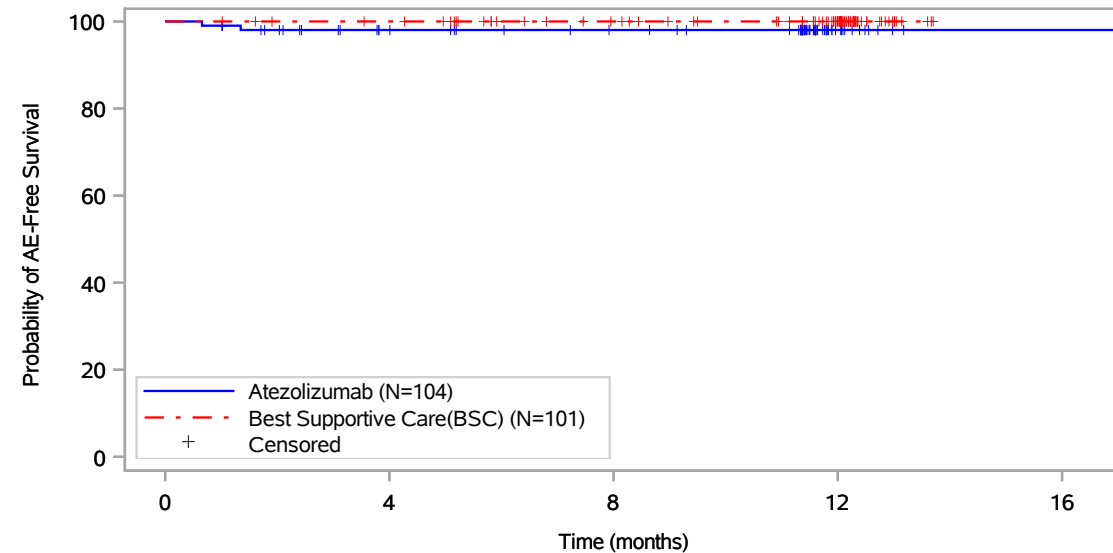
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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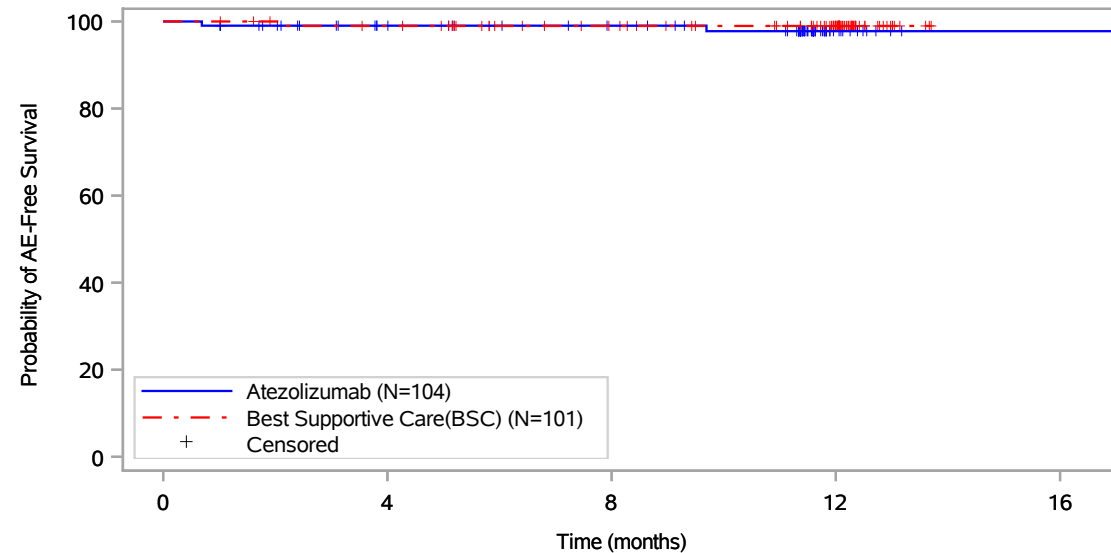
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	11	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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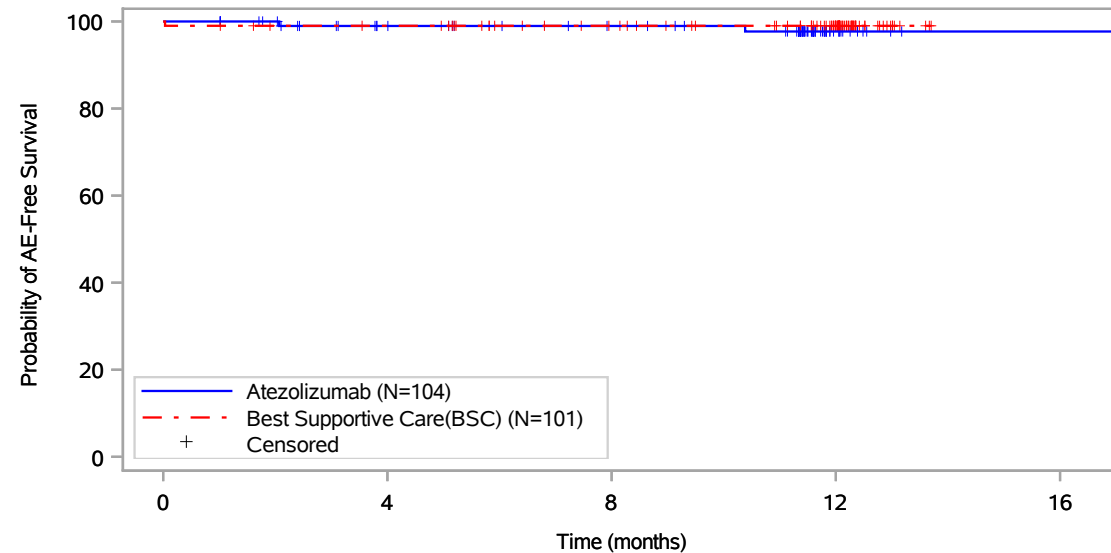
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hyperuricaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	96	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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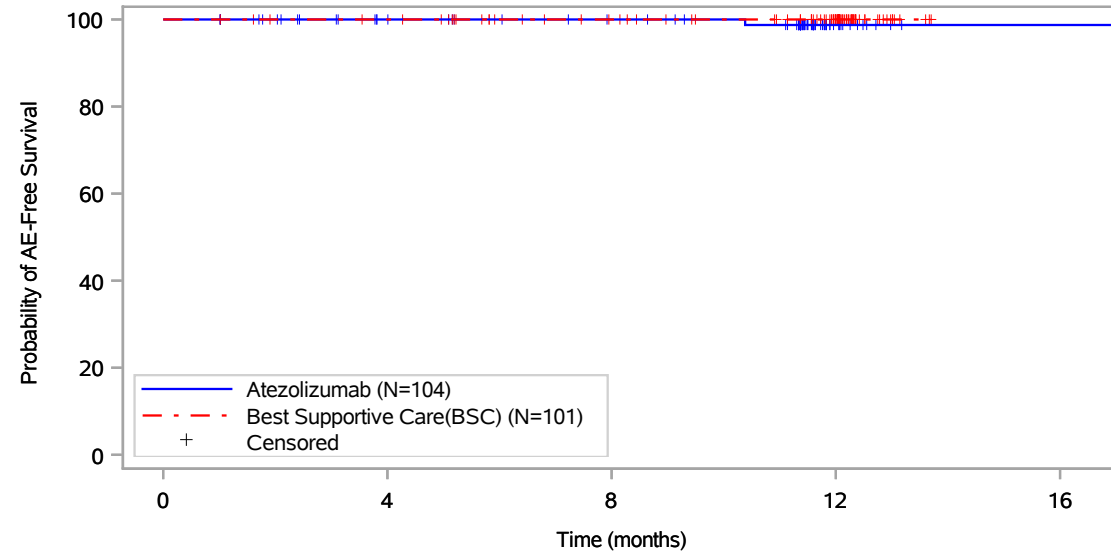
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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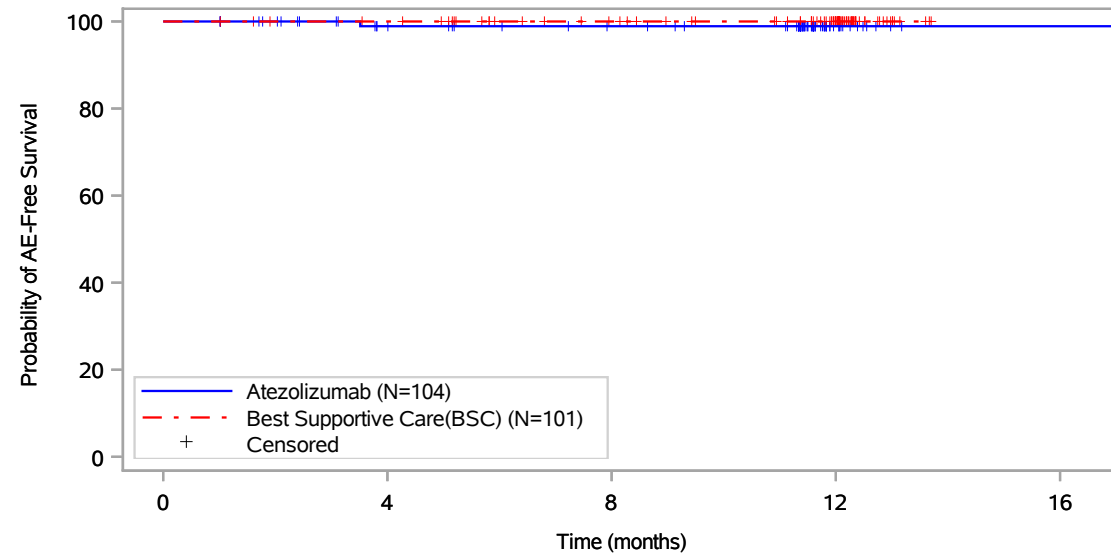
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypoglycaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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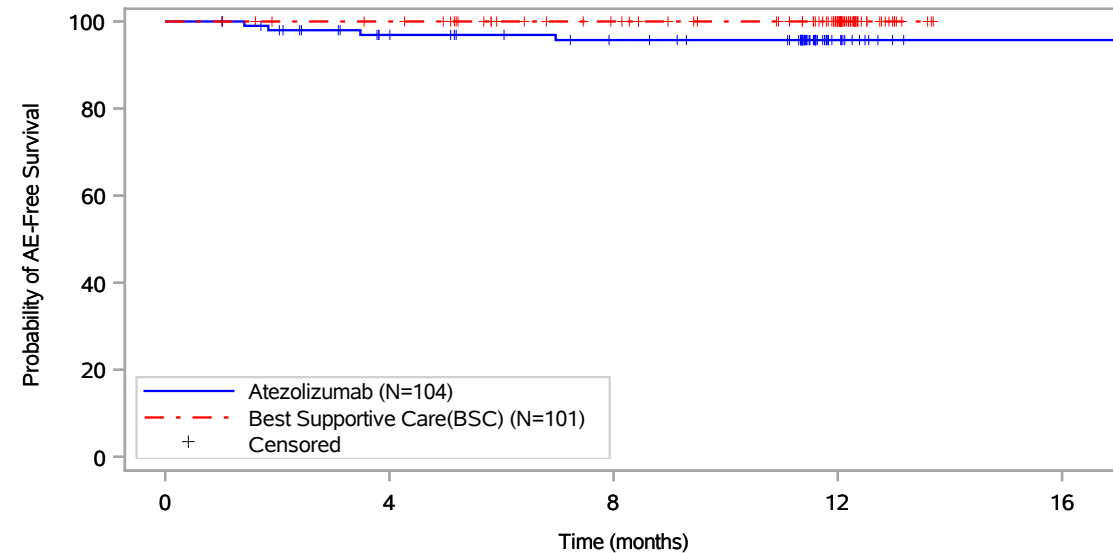
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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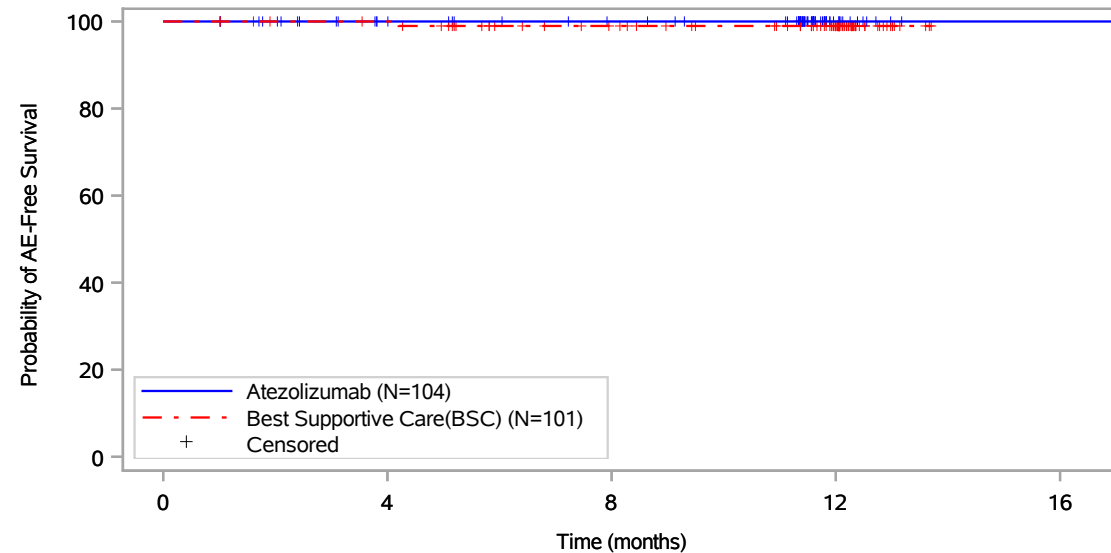
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypomagnesaemia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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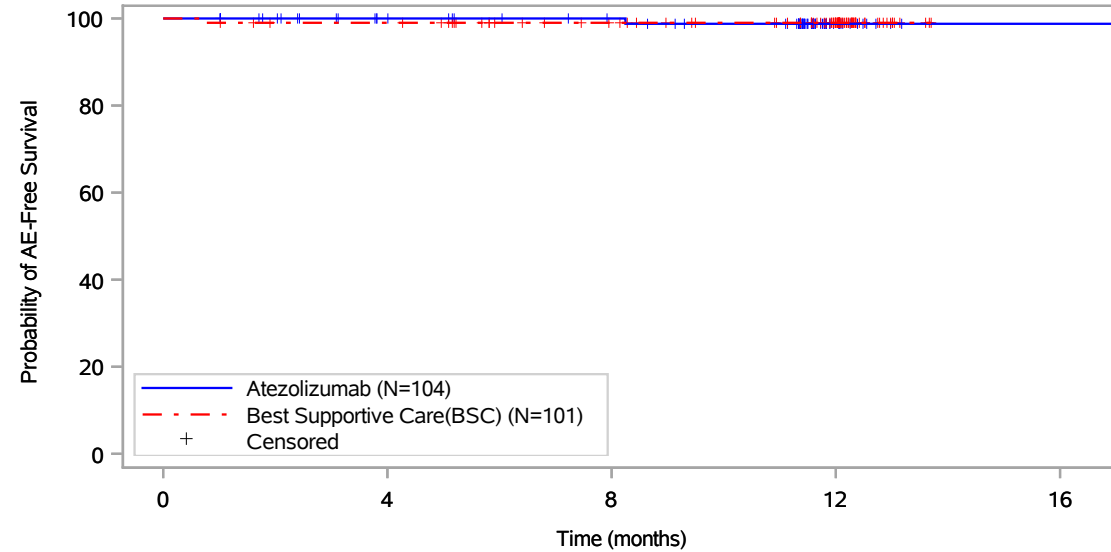
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	3	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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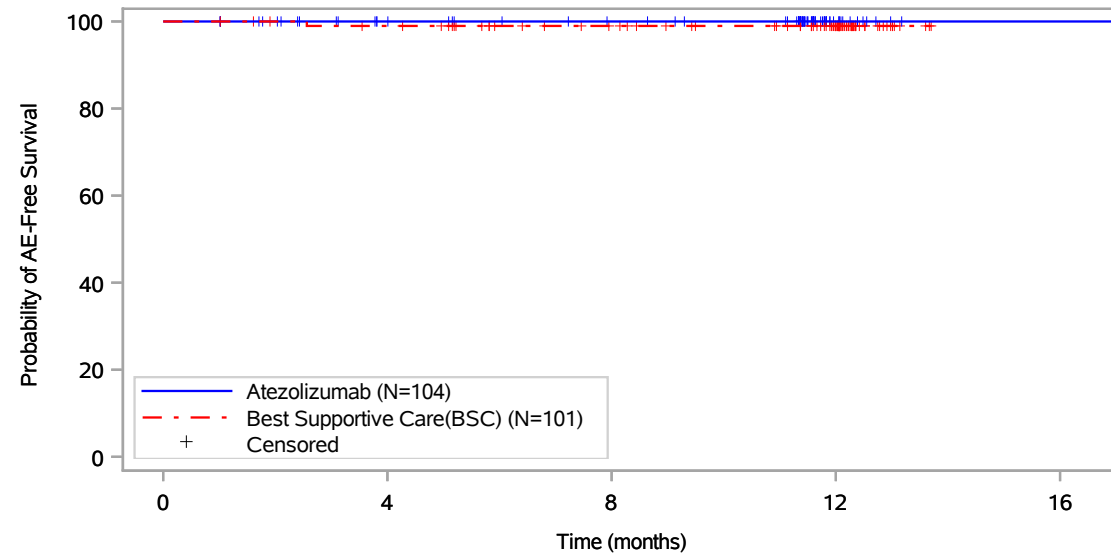
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypovolaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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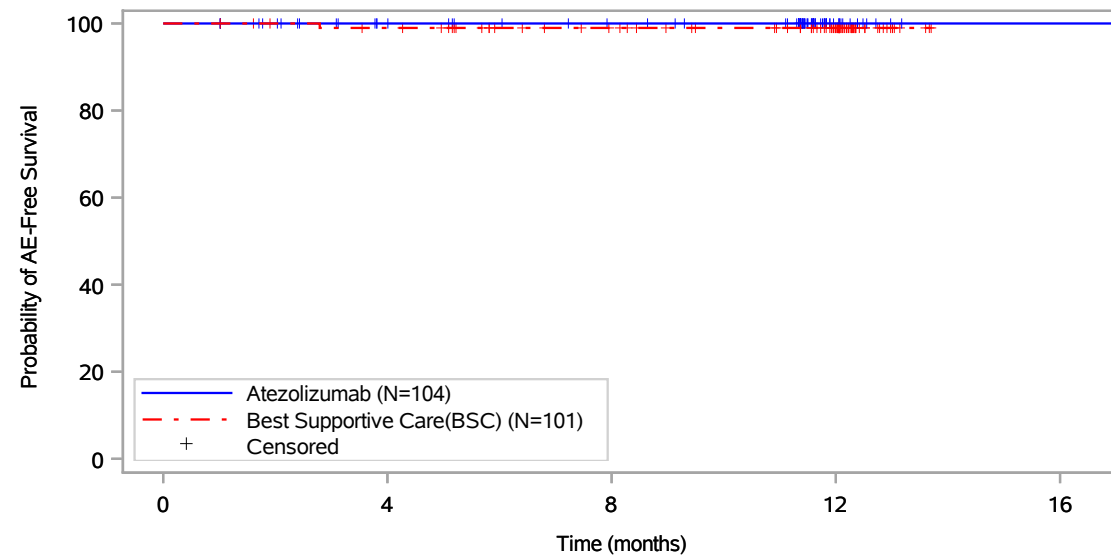
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Iron deficiency



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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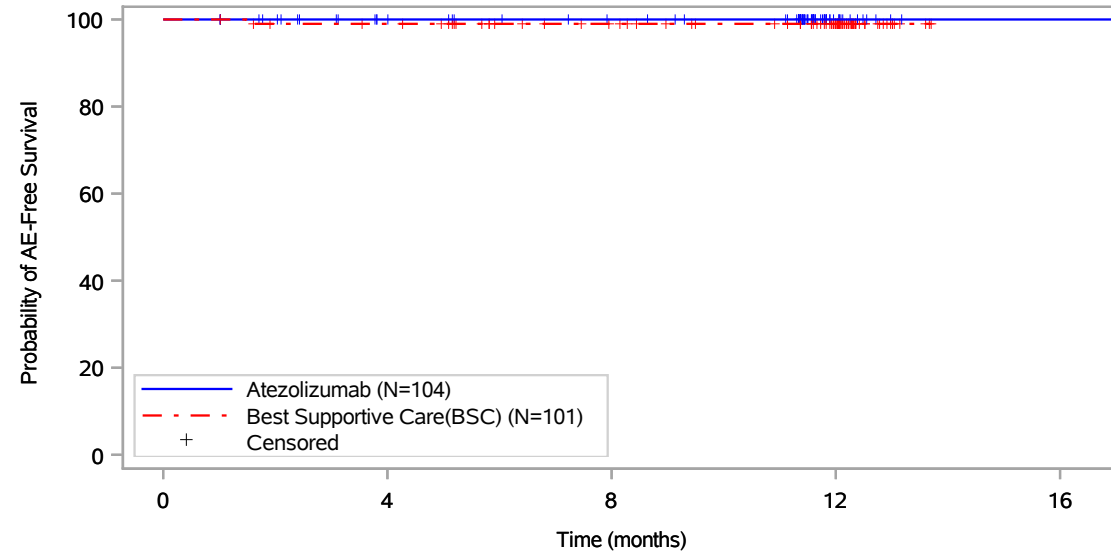
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Vitamin D deficiency



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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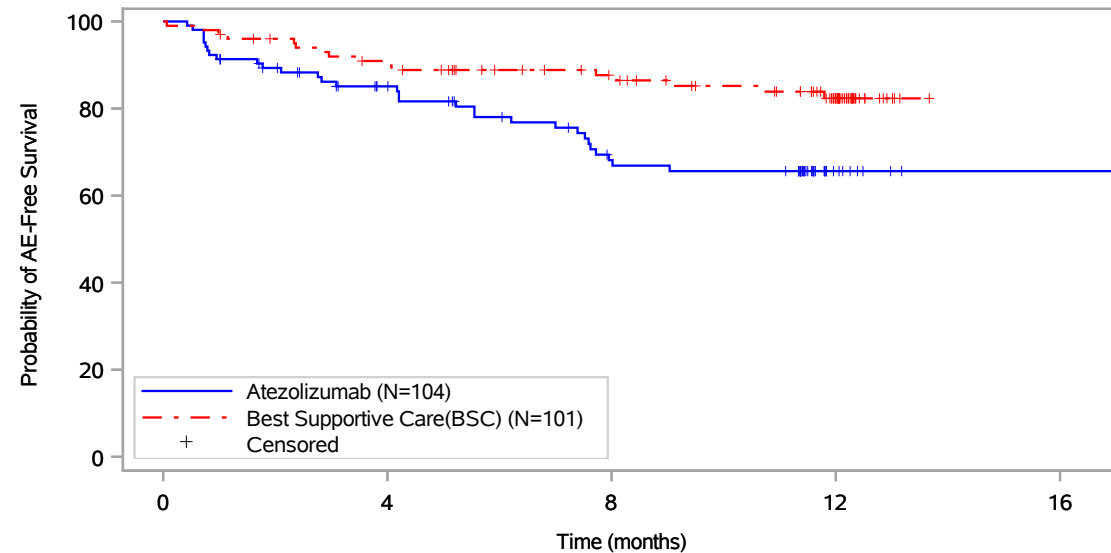
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk					
Atezolizumab (N=104)	104	75	54	8	1
Best Supportive Care(BSC) (N=101)	101	87	73	43	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	65	72
Best Supportive Care(BSC) (N=101)	0	4	16	42	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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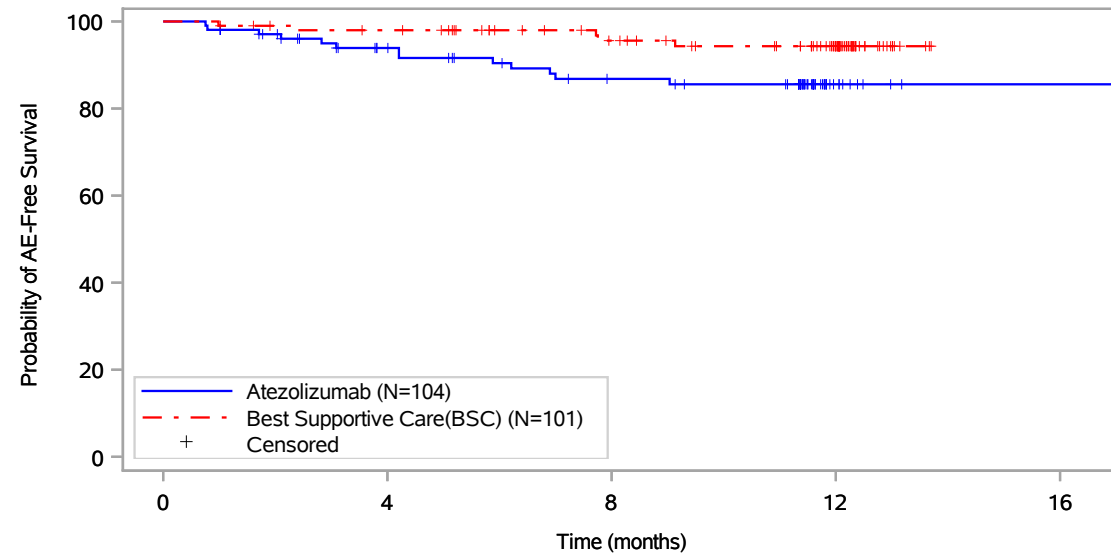
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Arthralgia



Patients at risk					
Atezolizumab (N=104)	104	83	70	9	1
Best Supportive Care(BSC) (N=101)	101	95	79	52	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	82	90
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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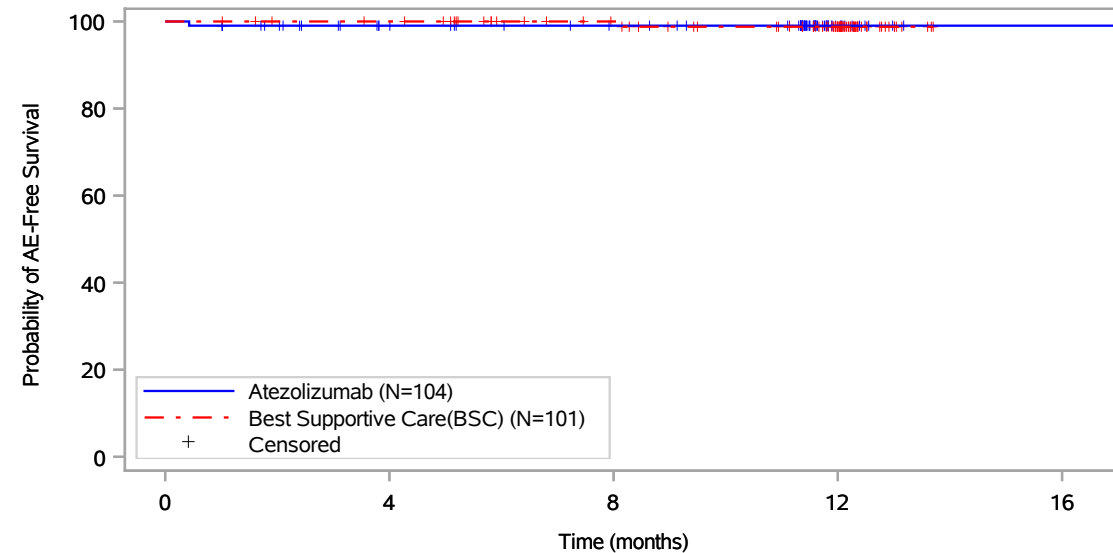
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Arthritis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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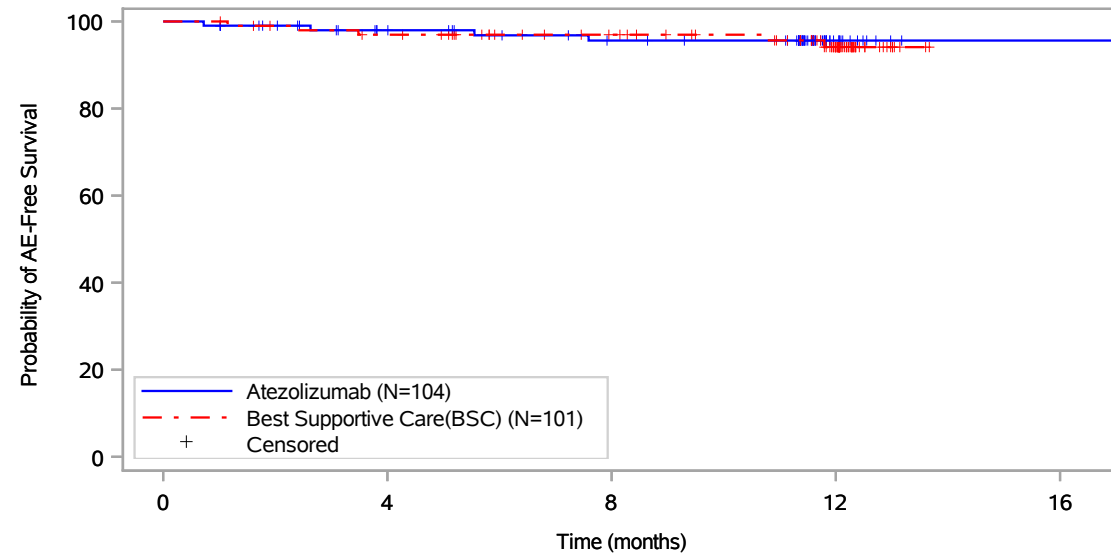
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Back pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	79	13	1
Best Supportive Care(BSC) (N=101)	101	94	80	50	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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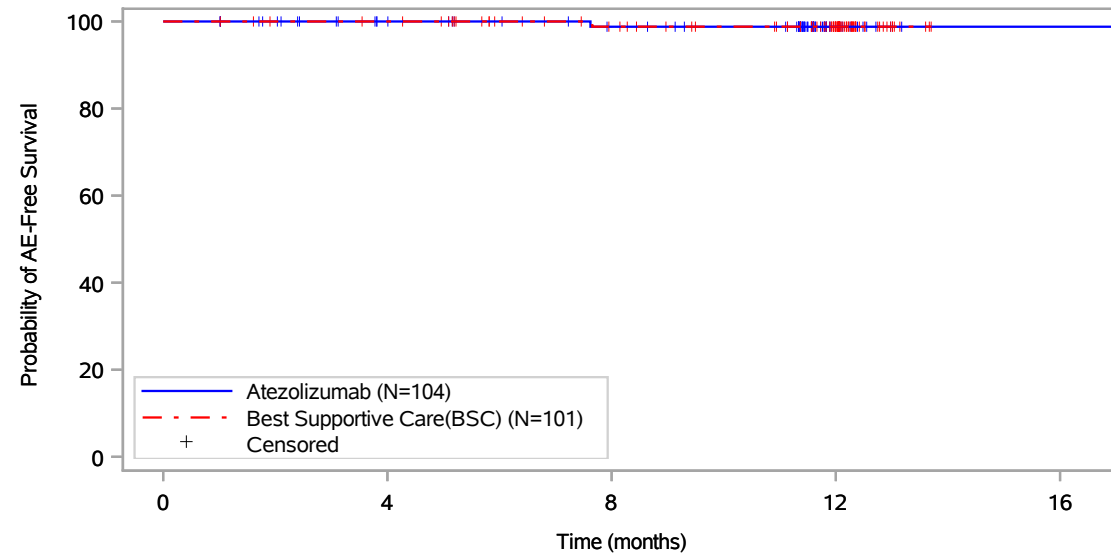
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Bone pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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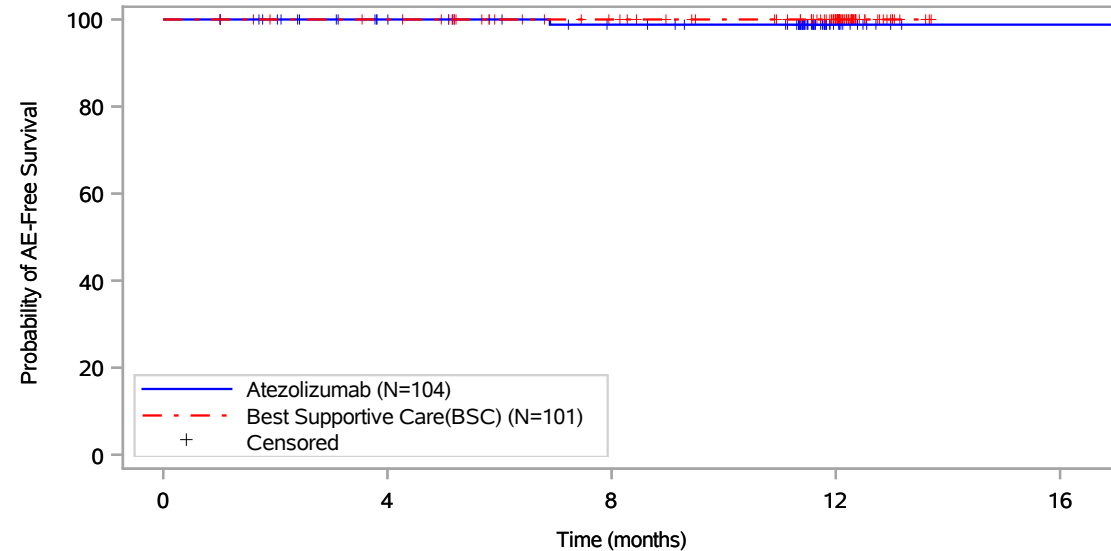
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Coccydynia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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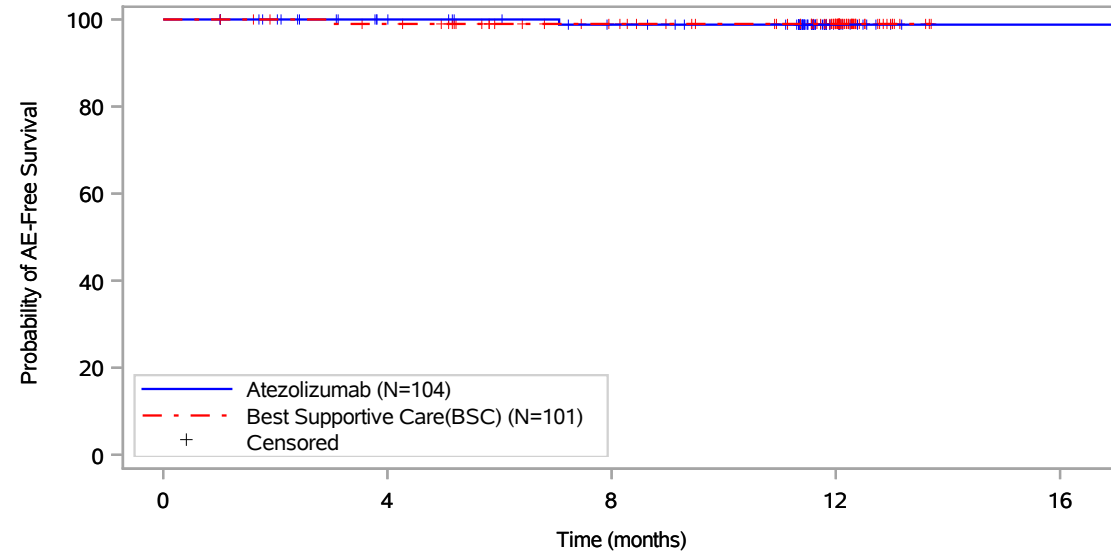
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Dupuytren's contracture



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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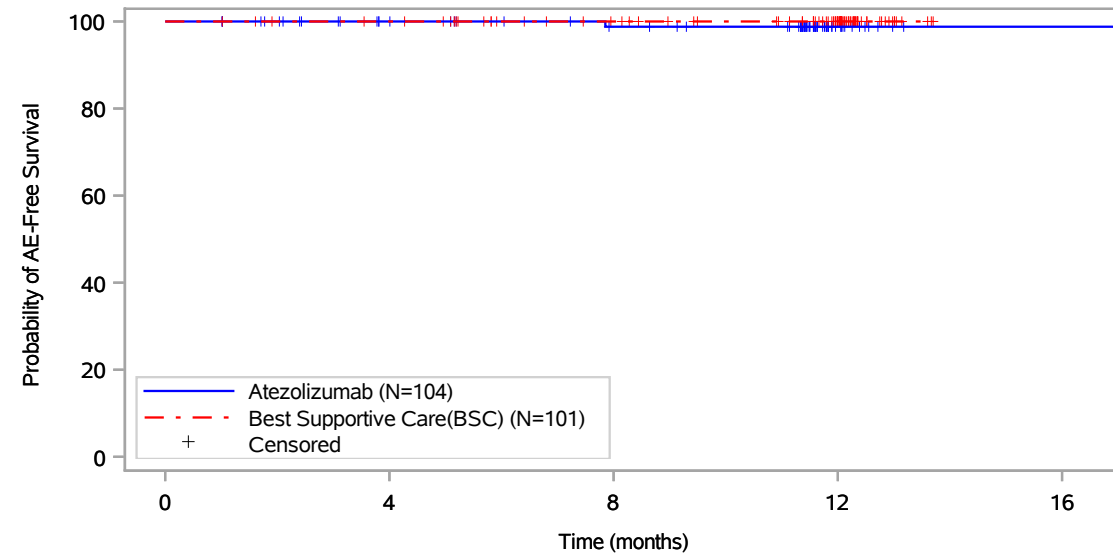
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Limb discomfort



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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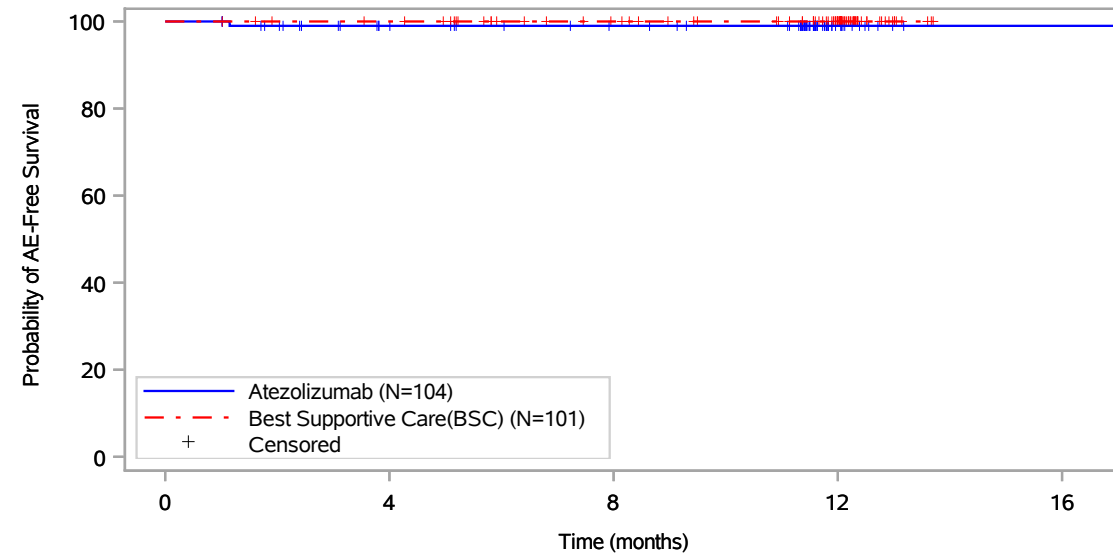
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscle fatigue



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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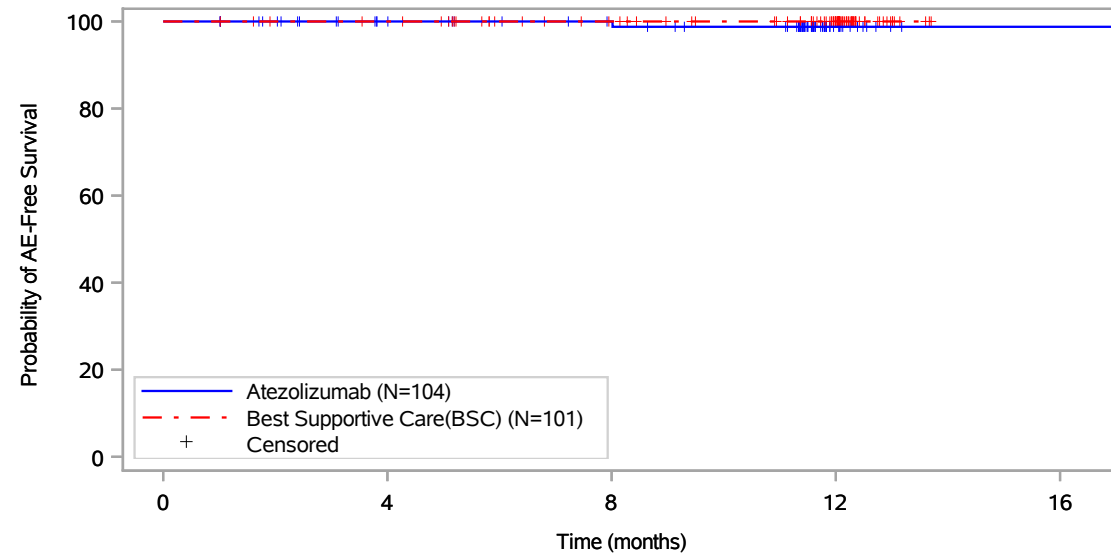
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscle spasms



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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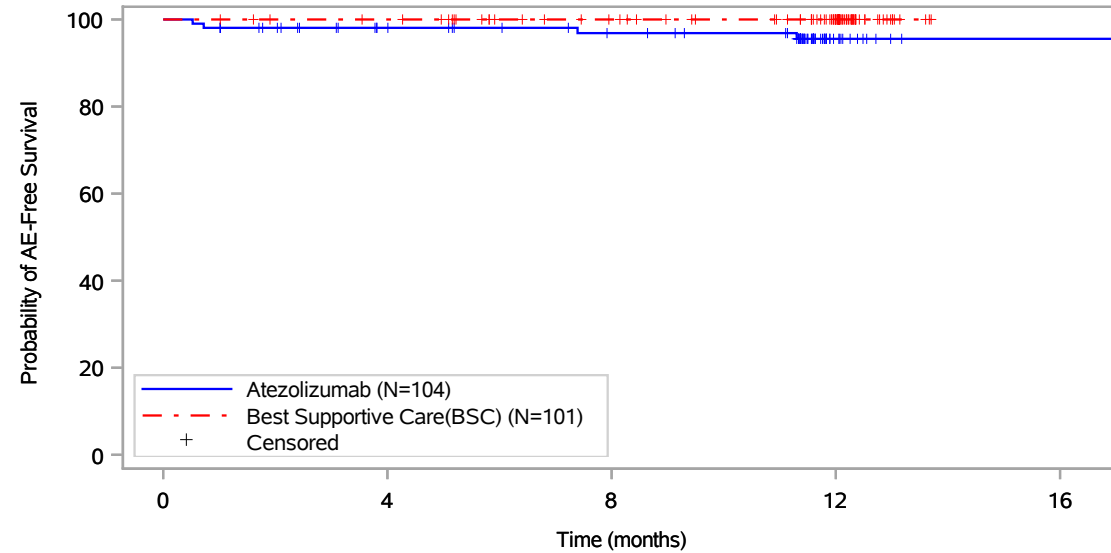
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk					
Atezolizumab (N=104)	104	87	79	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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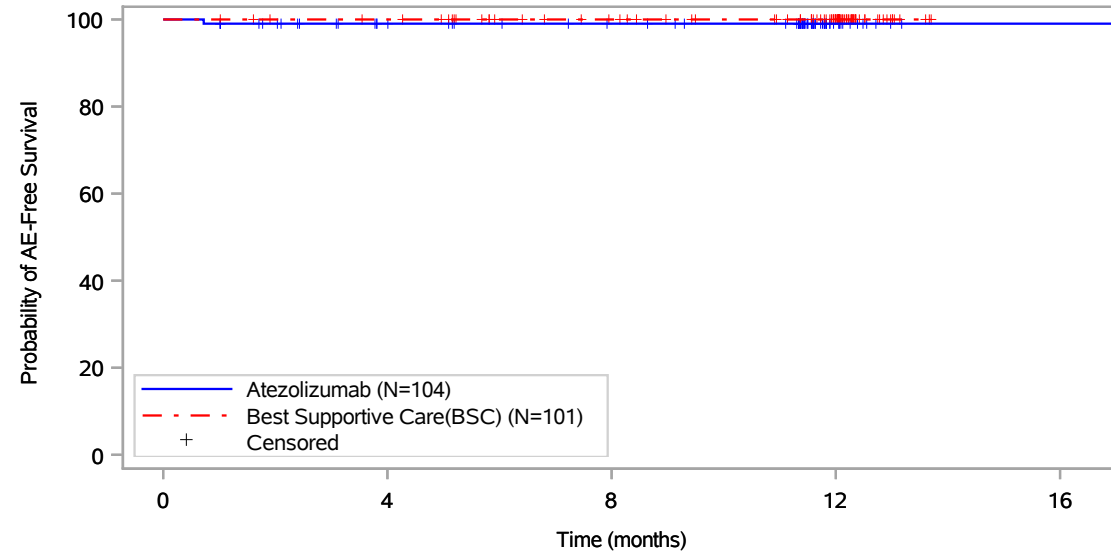
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal chest pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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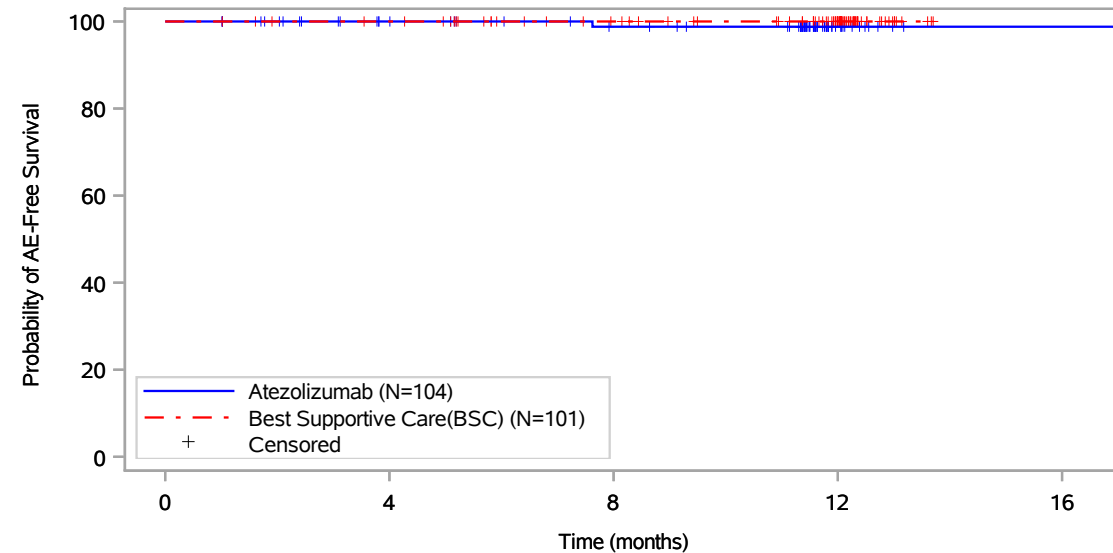
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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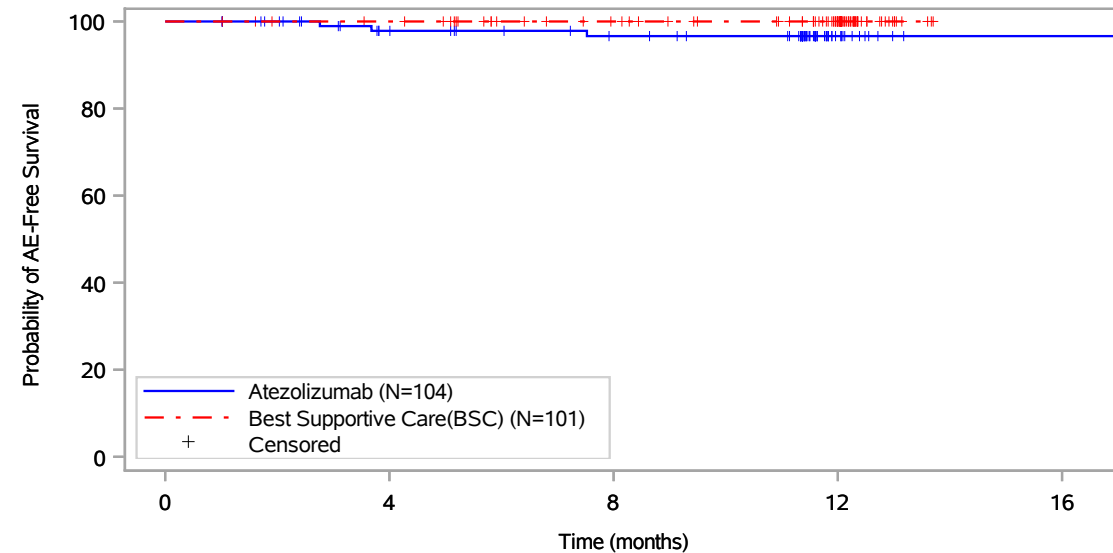
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal stiffness



Patients at risk					
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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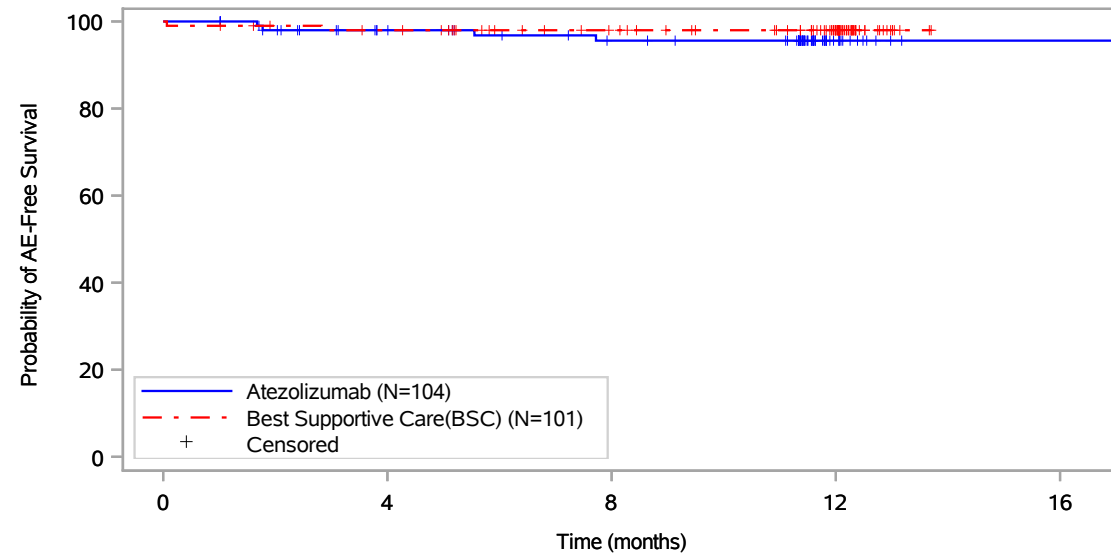
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	78	13	1
Best Supportive Care(BSC) (N=101)	101	95	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	99
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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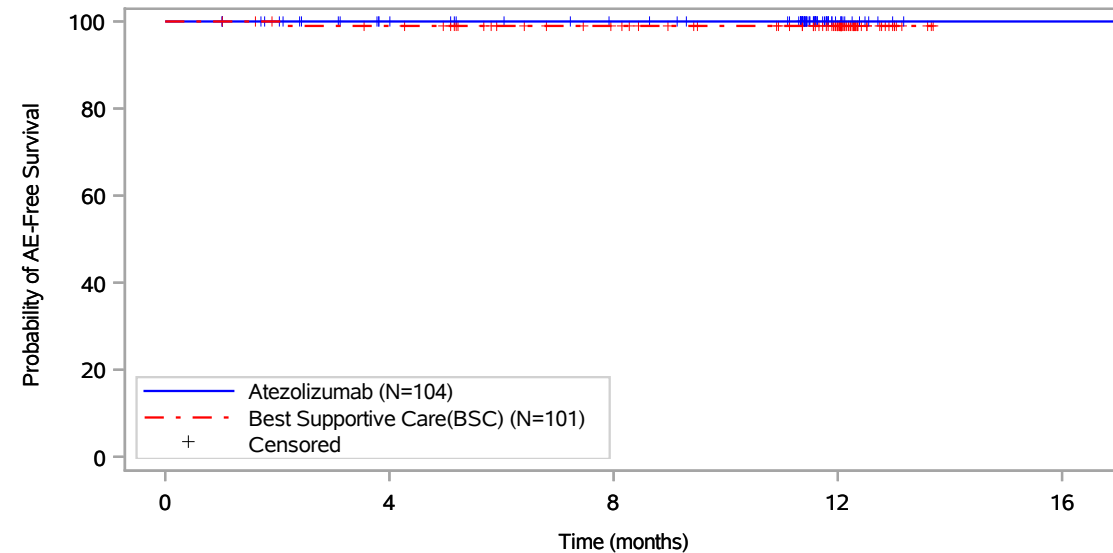
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Neck pain



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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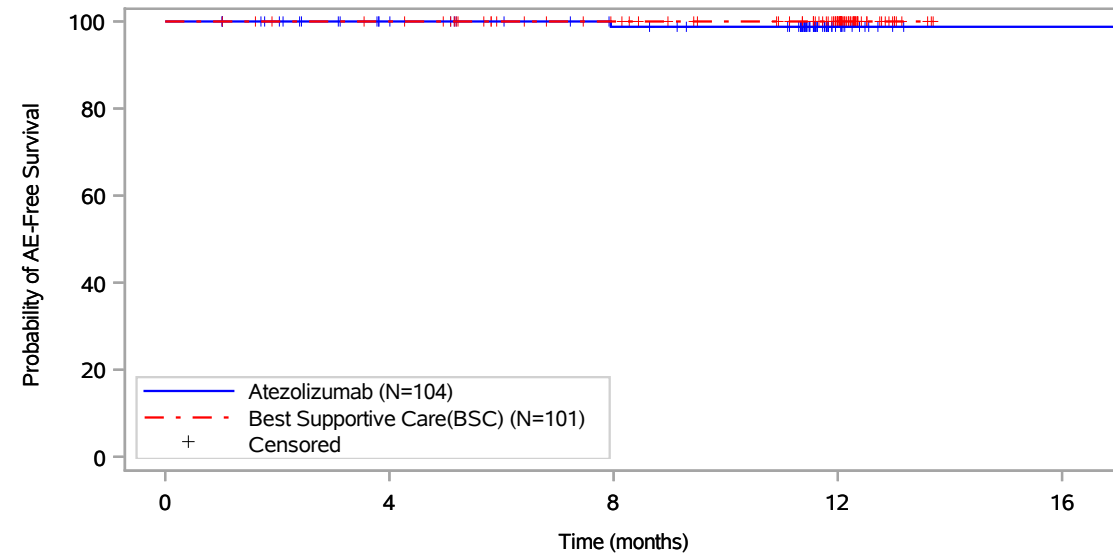
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Osteoarthritis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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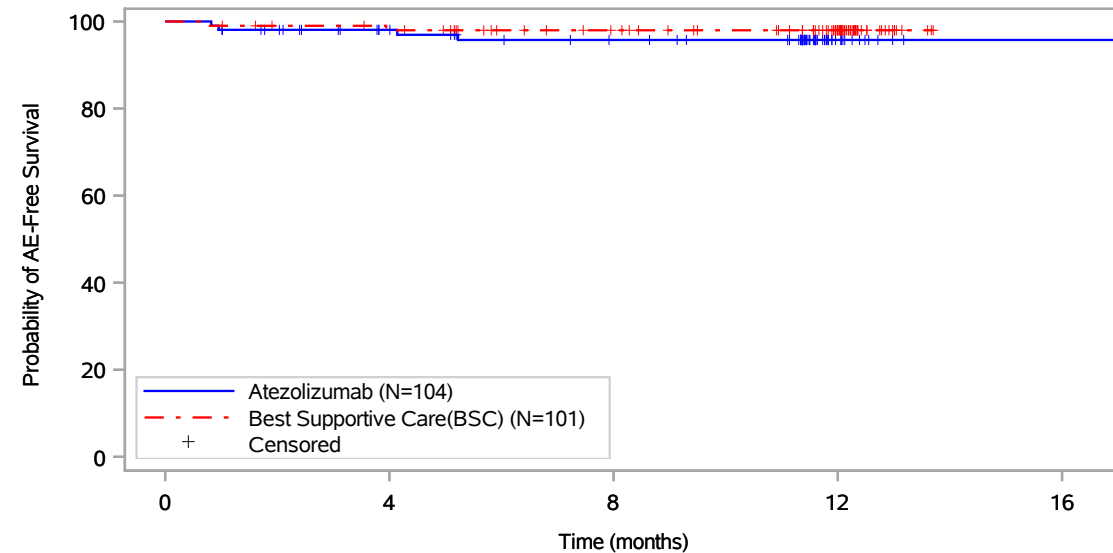
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Pain in extremity



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	78	13	1
Best Supportive Care(BSC) (N=101)	101	95	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	99
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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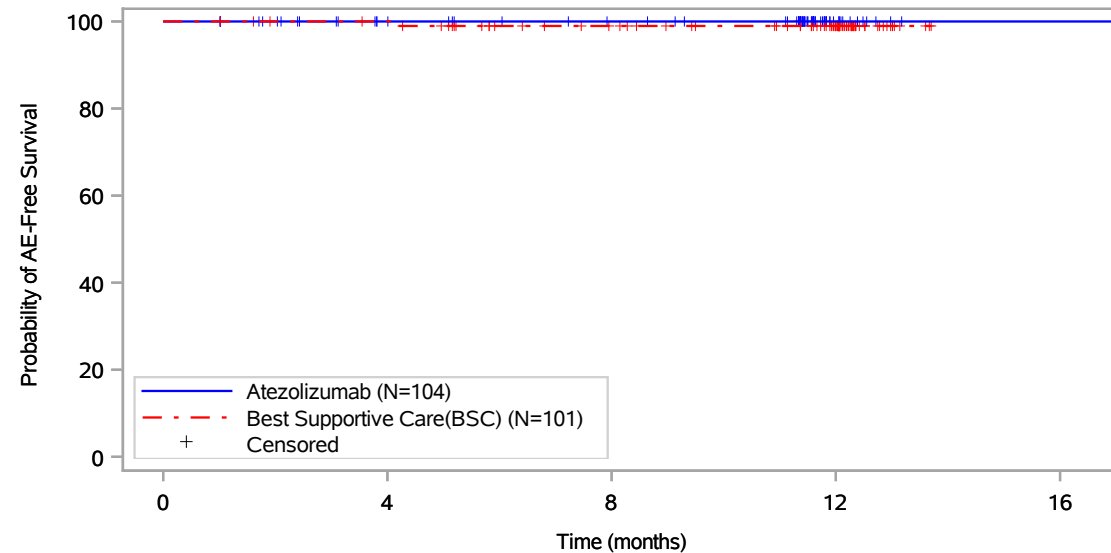
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Peri-arthritis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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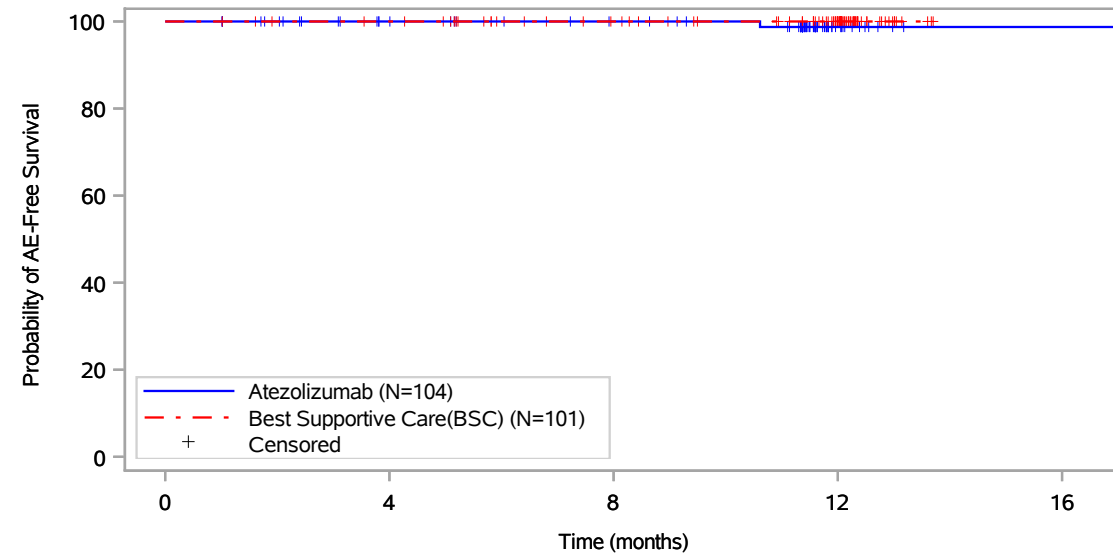
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Rotator cuff syndrome



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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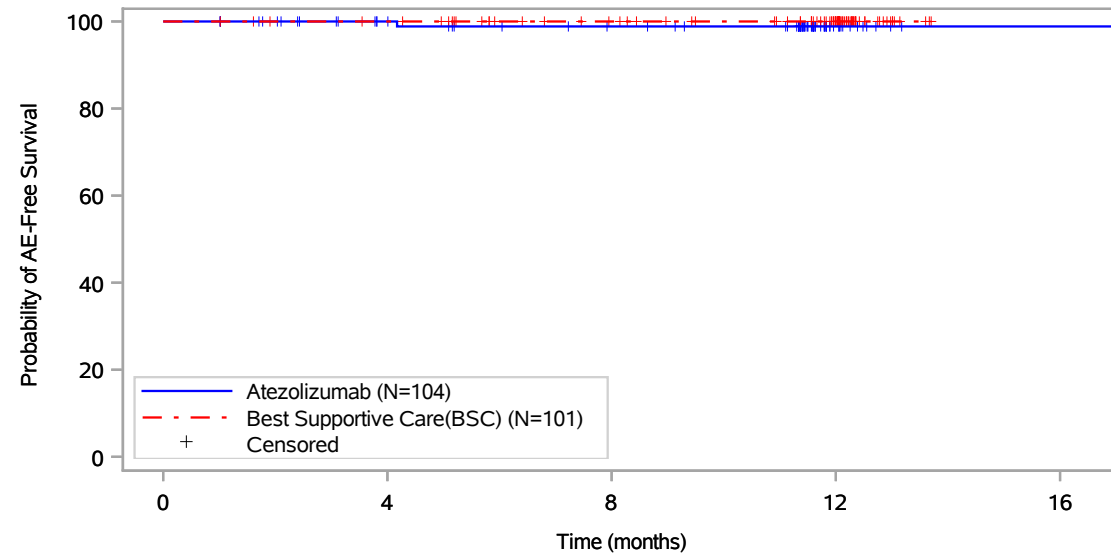
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Spinal pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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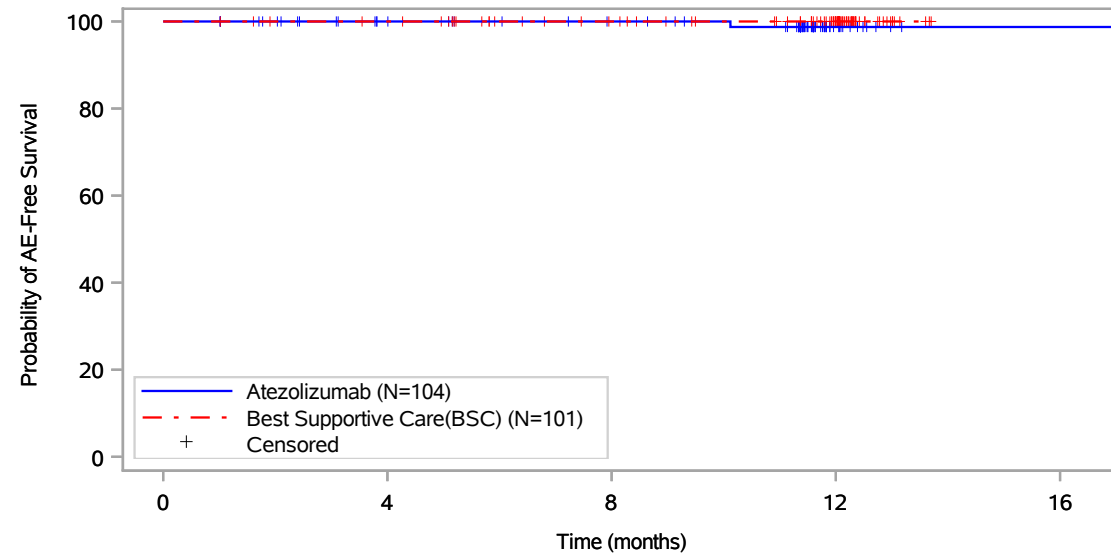
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Synovial cyst



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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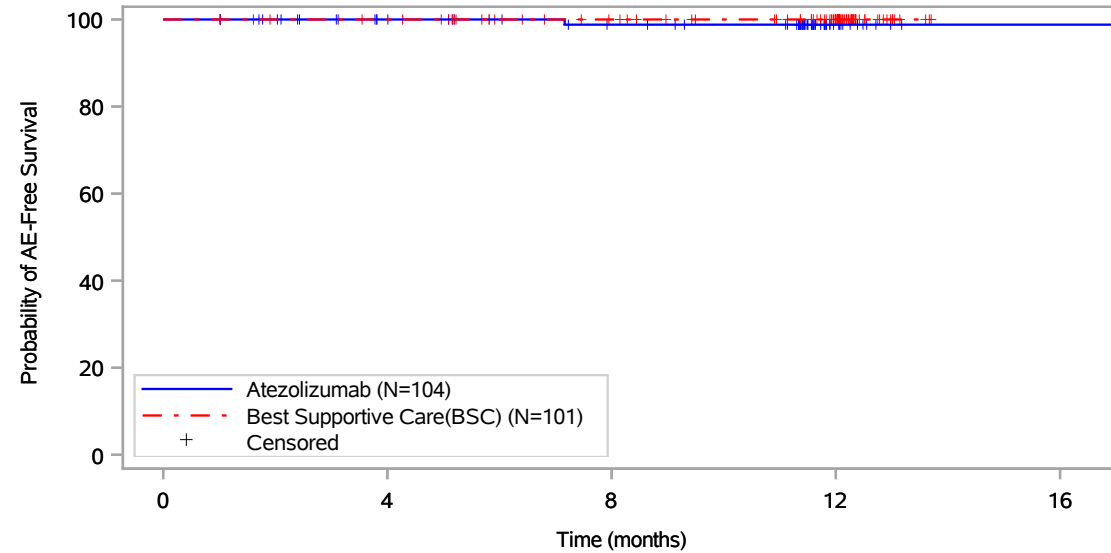
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Tendonitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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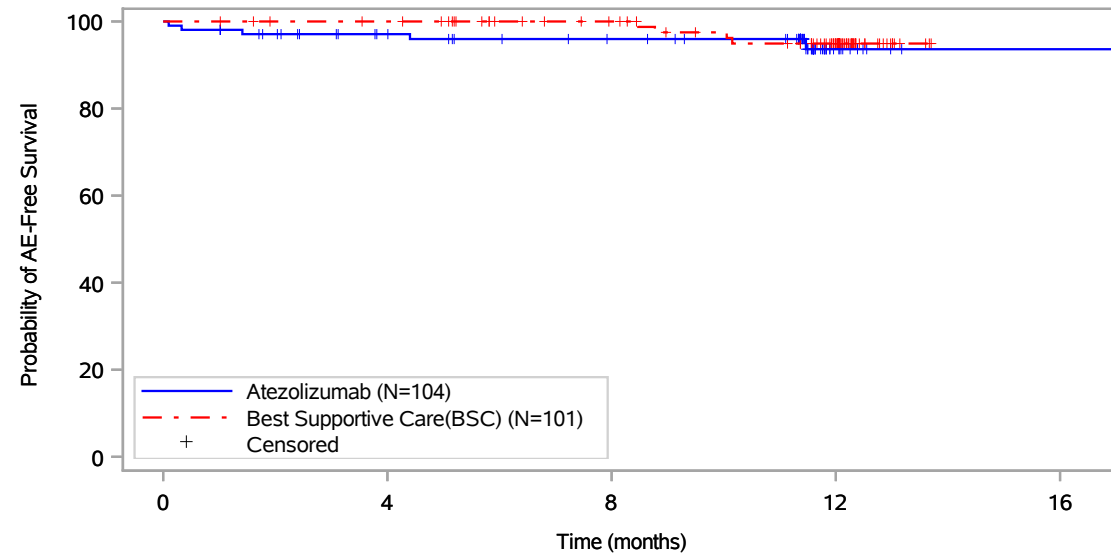
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	11	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	88	98
Best Supportive Care(BSC) (N=101)	0	4	18	42	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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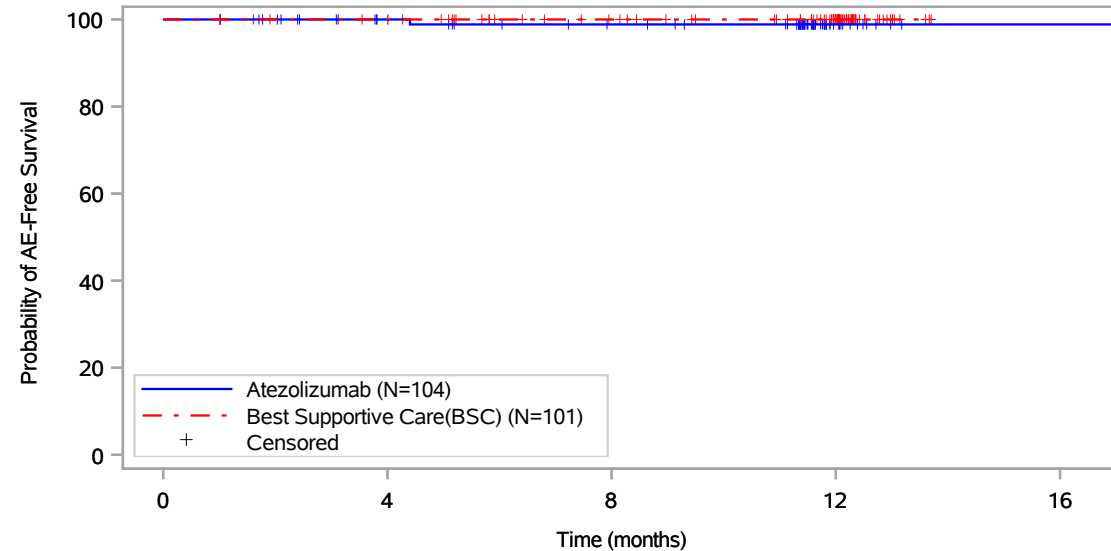
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Basal cell carcinoma



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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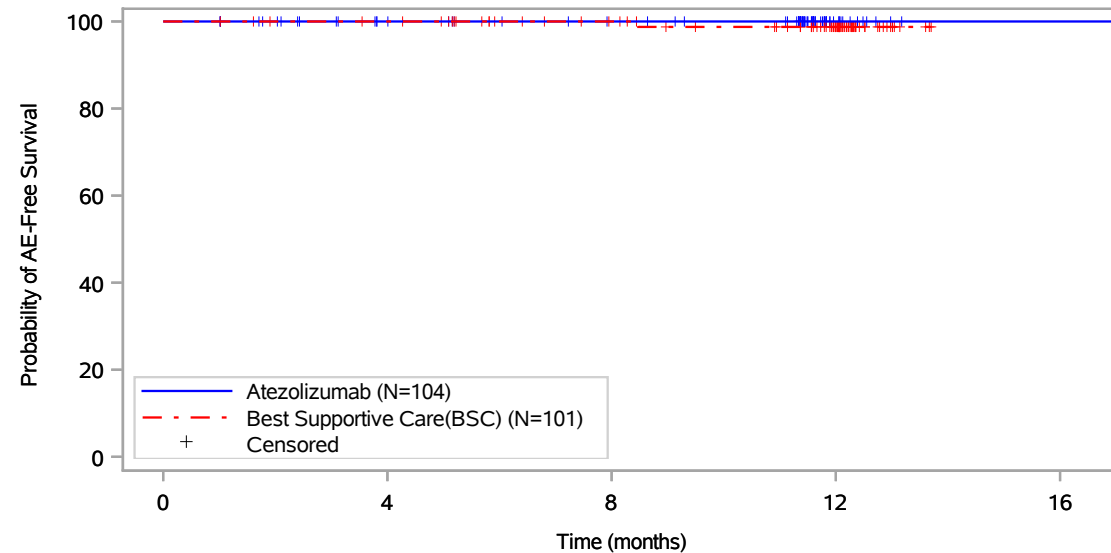
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Breast cancer



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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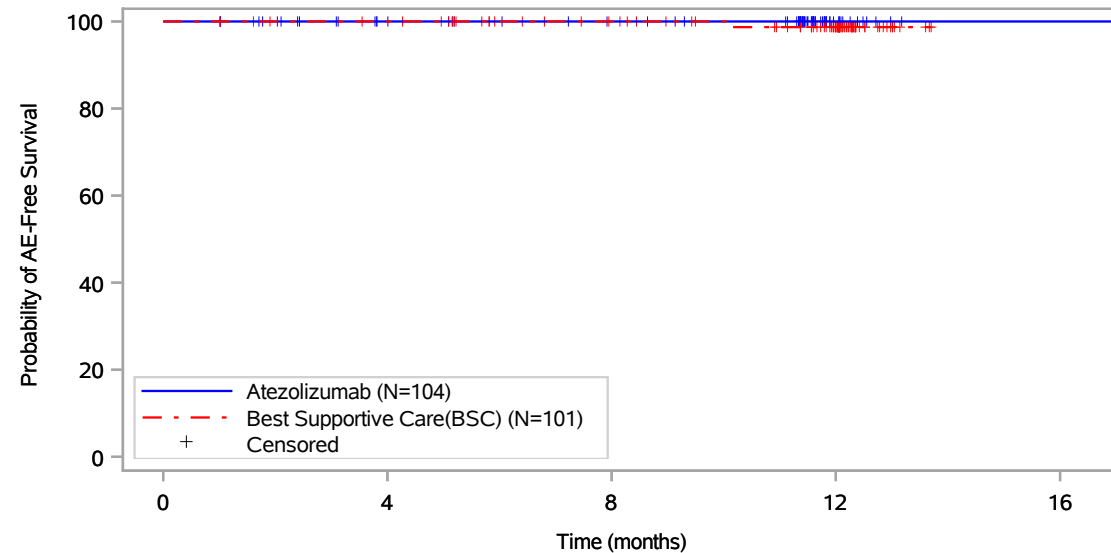
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Fibroma



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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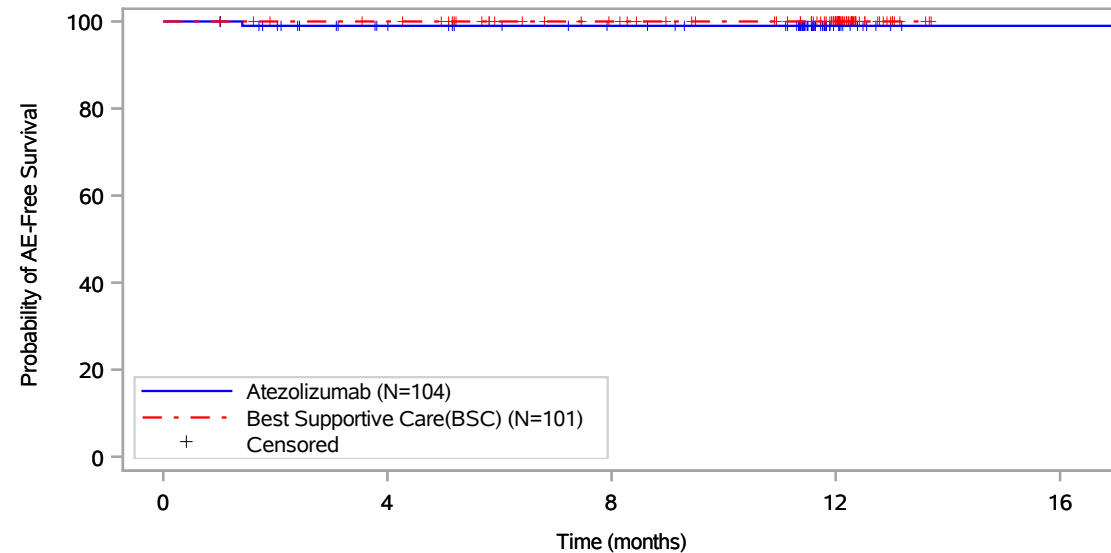
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Histiocytosis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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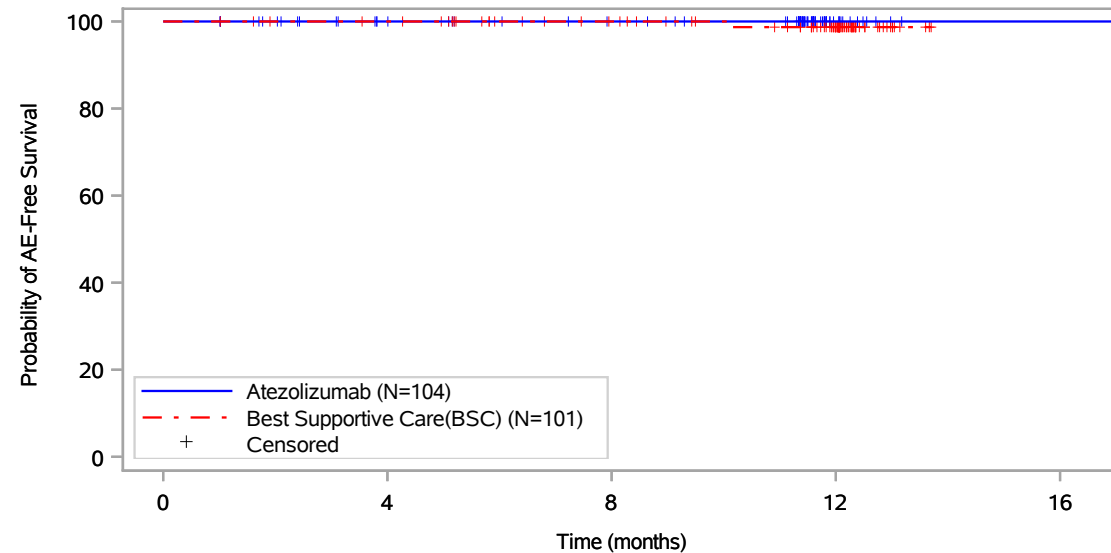
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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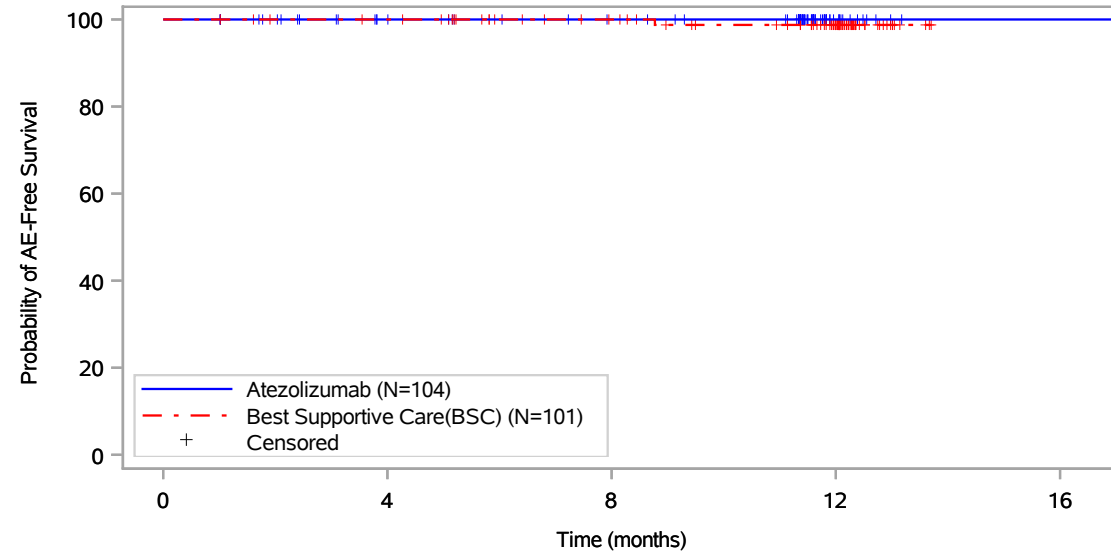
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Prostate cancer



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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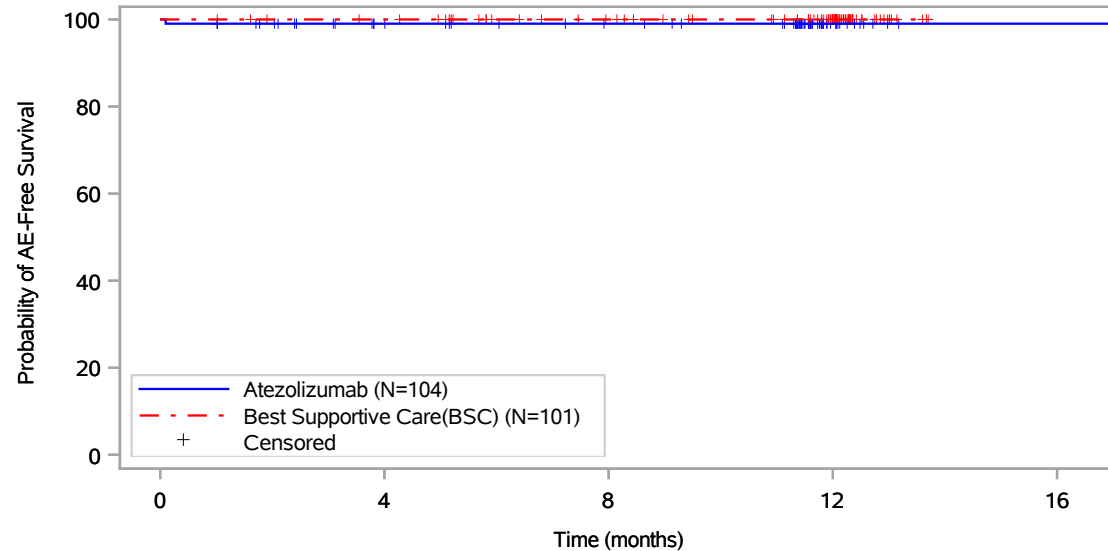
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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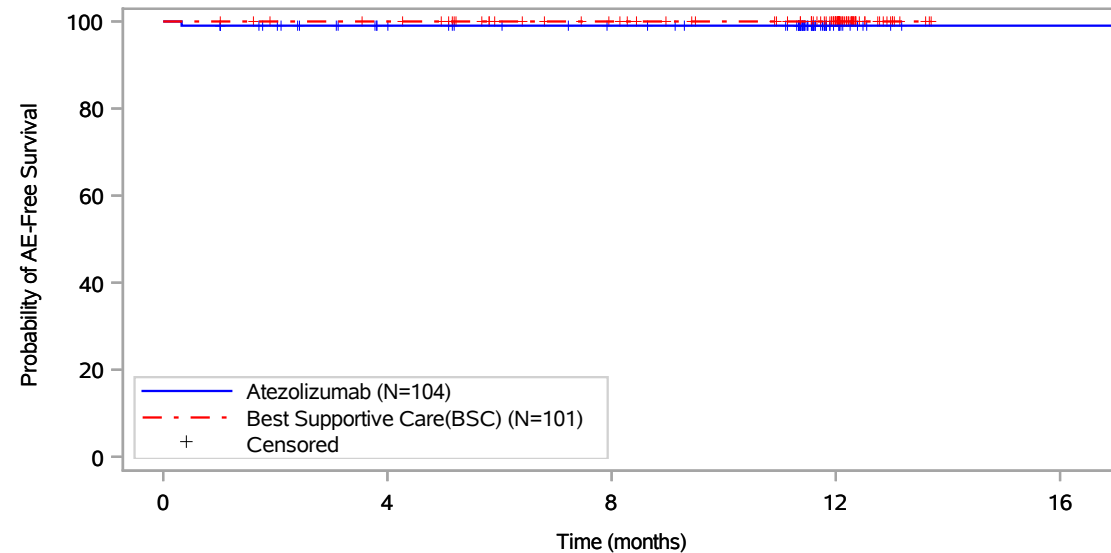
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Seborrhoeic keratosis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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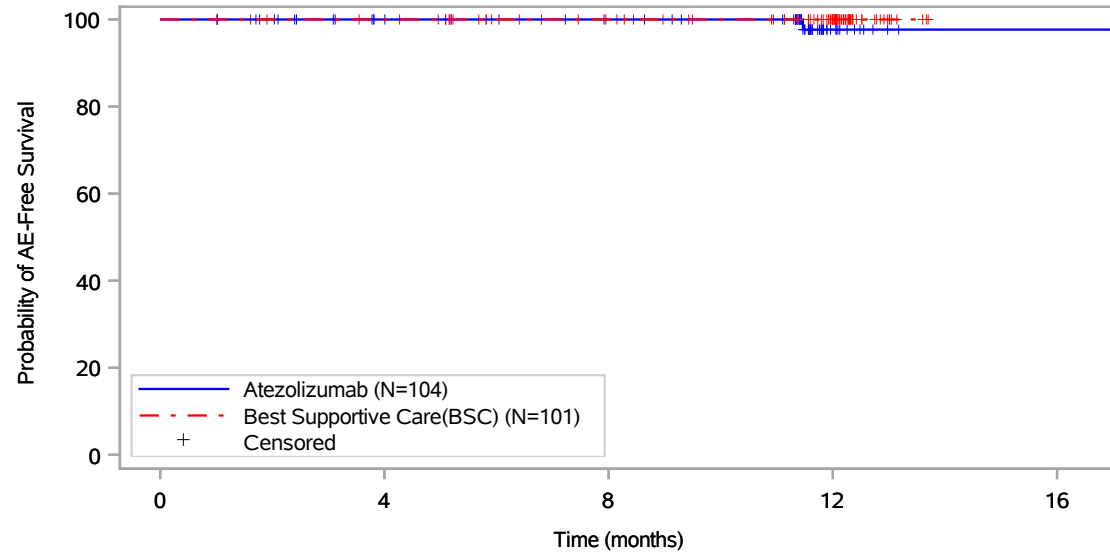
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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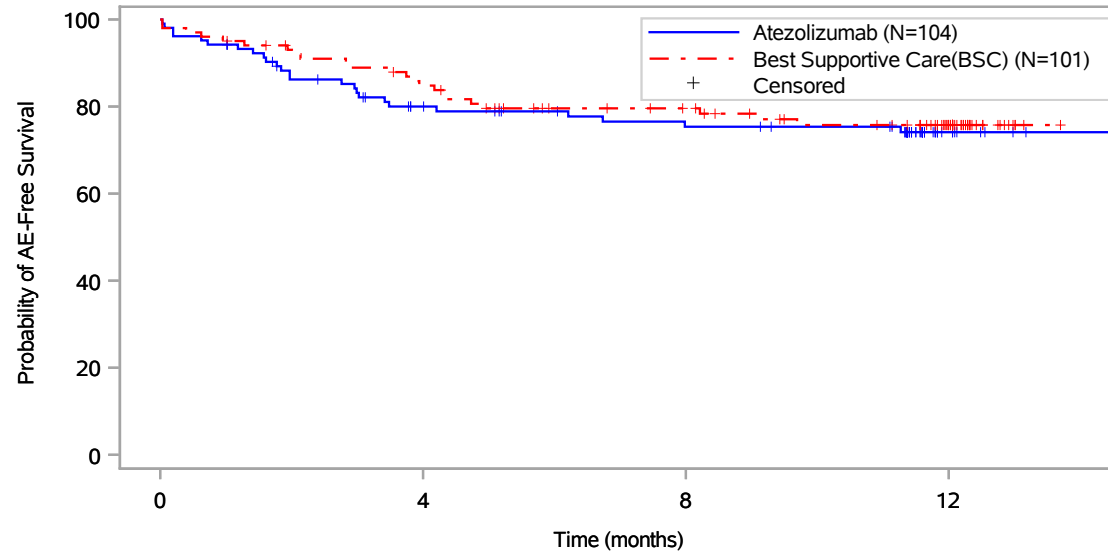
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	73	64	9
Best Supportive Care(BSC) (N=101)	101	82	66	39
Patients censored				
Atezolizumab (N=104)	0	11	16	70
Best Supportive Care(BSC) (N=101)	0	4	15	39

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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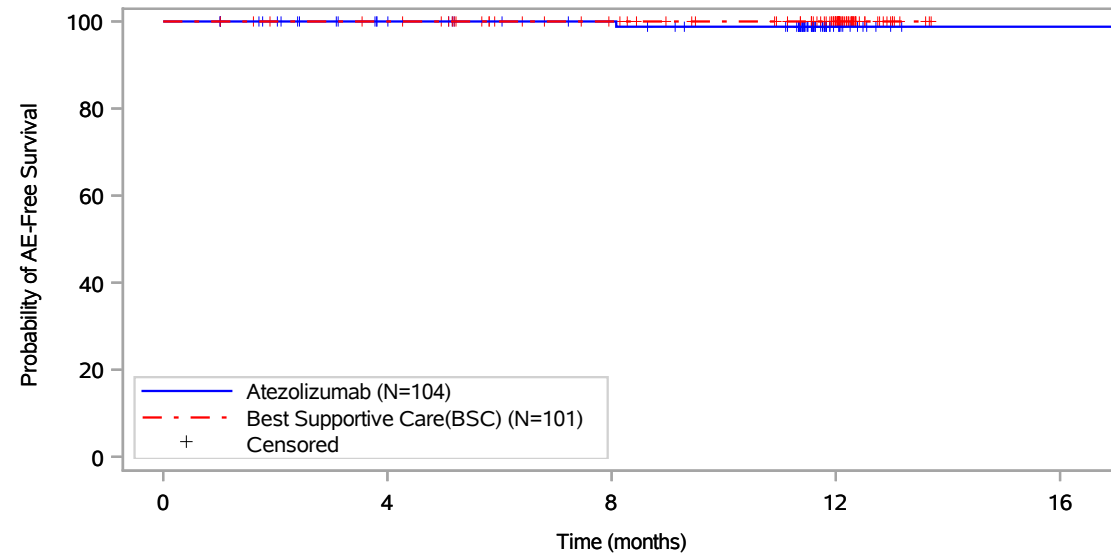
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Arachnoid cyst



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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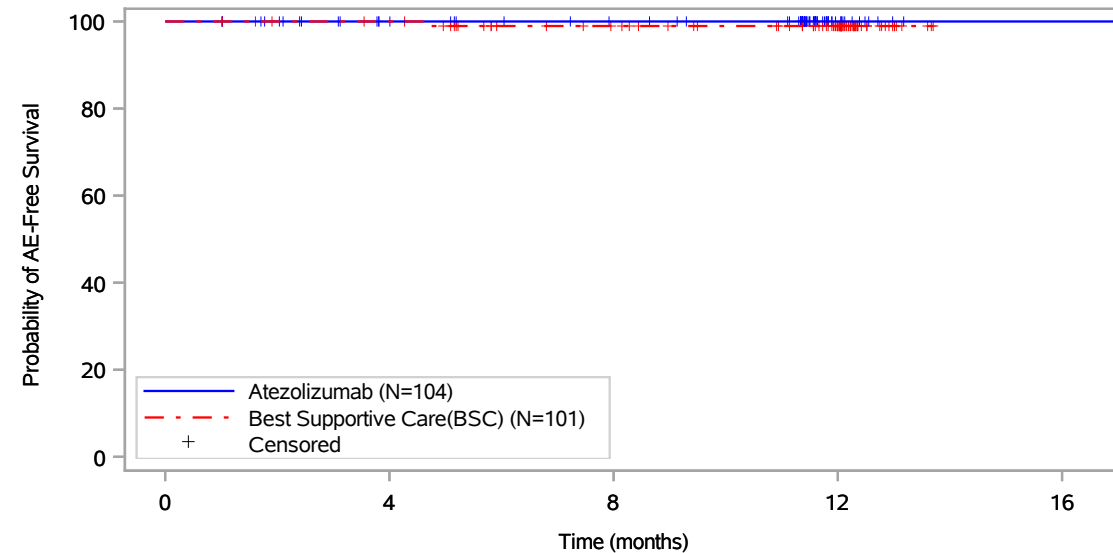
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Brain oedema



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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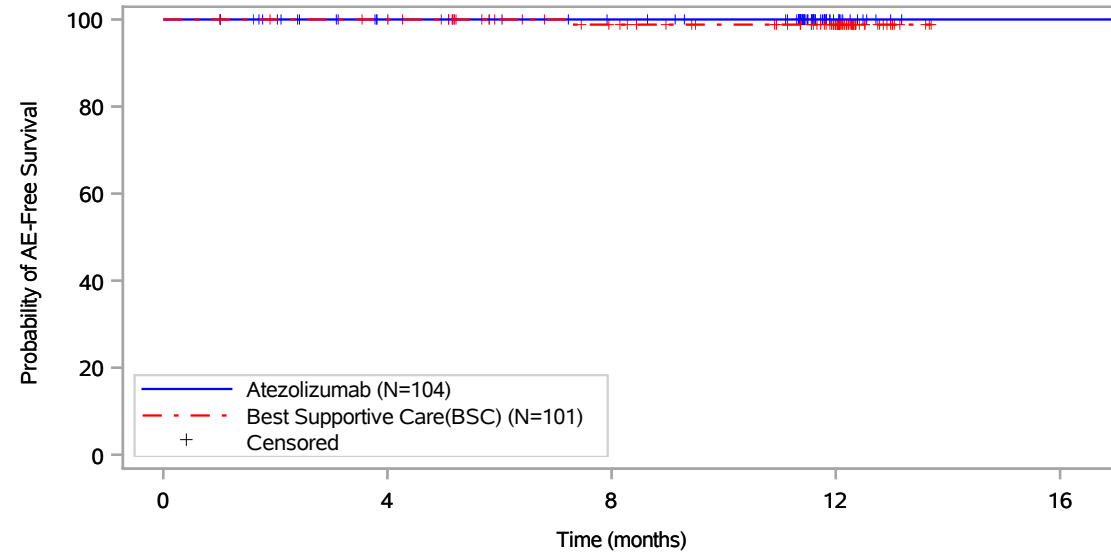
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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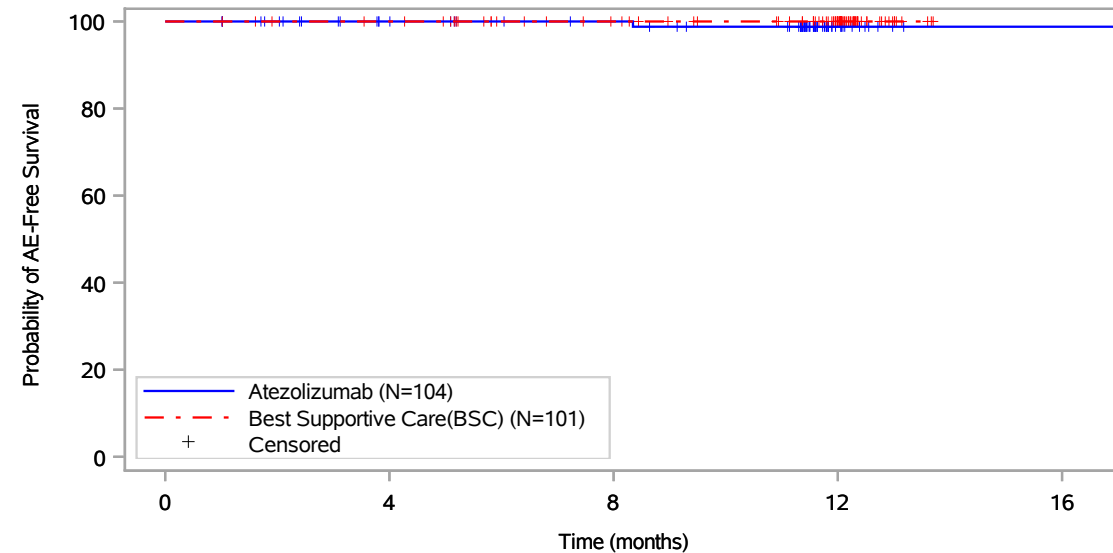
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebral arteriosclerosis



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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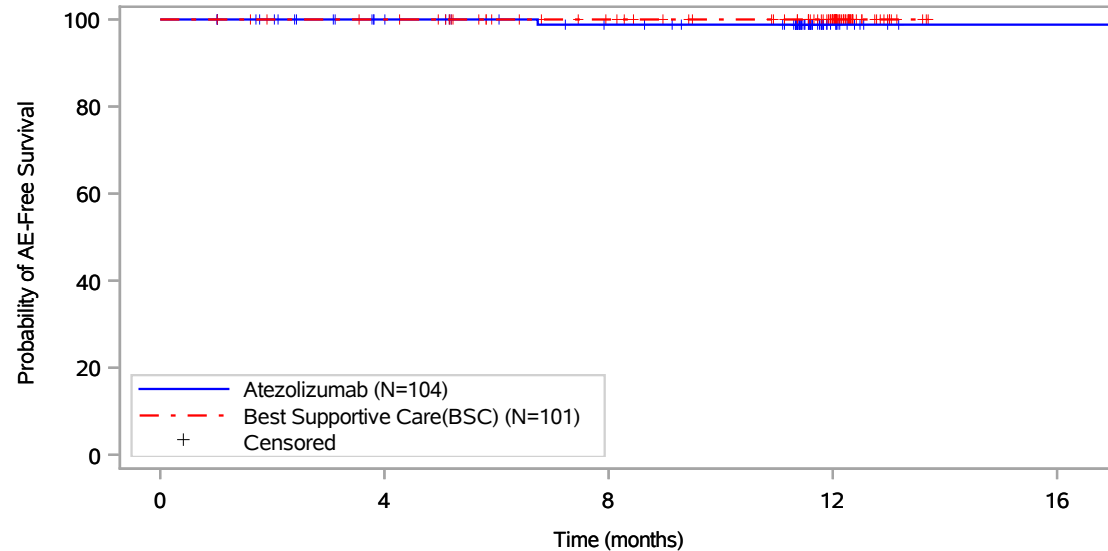
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebral infarction



Patients at risk					
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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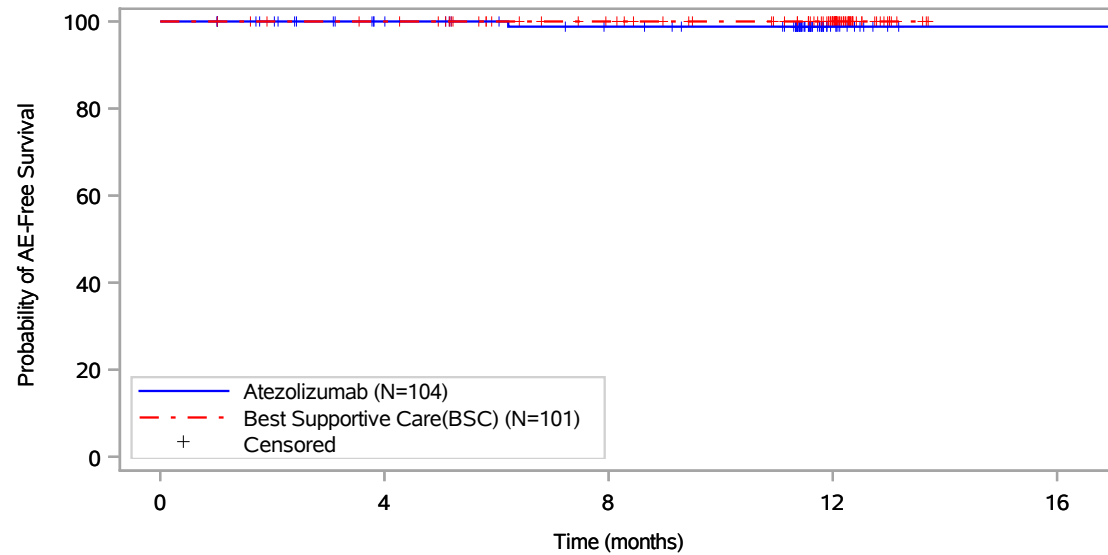
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Cognitive disorder



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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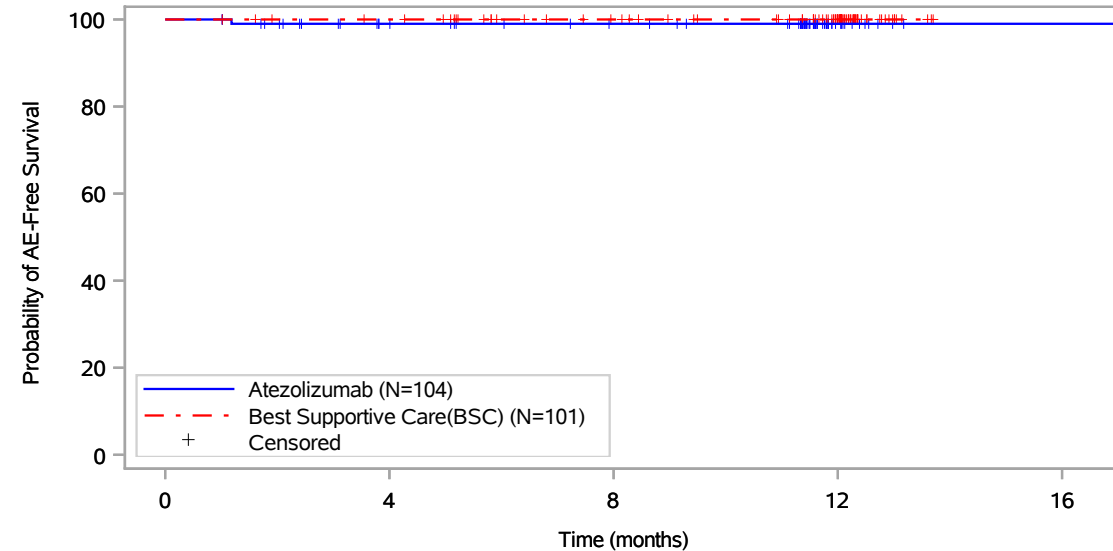
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

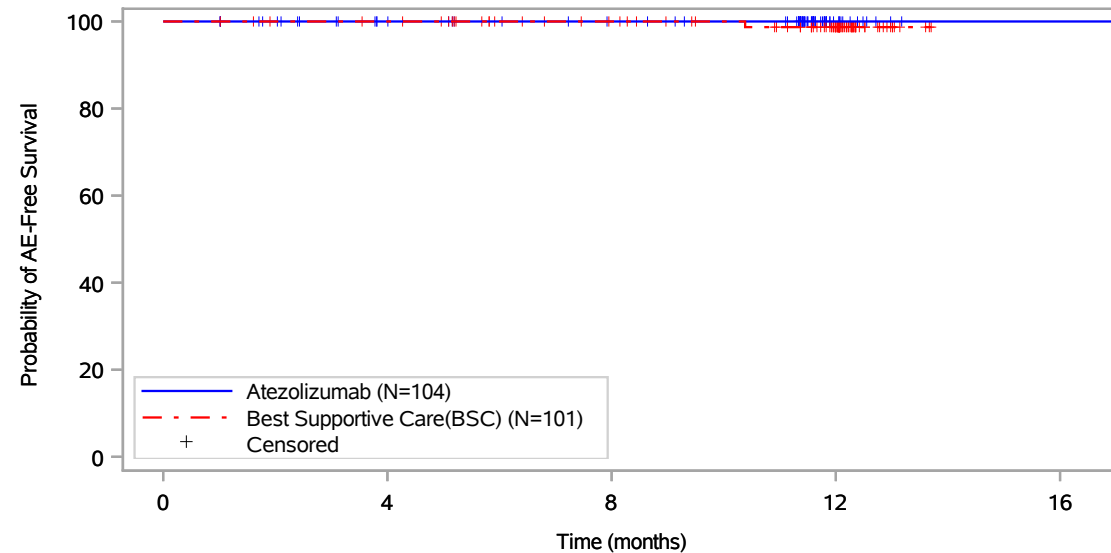
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Disturbance in attention



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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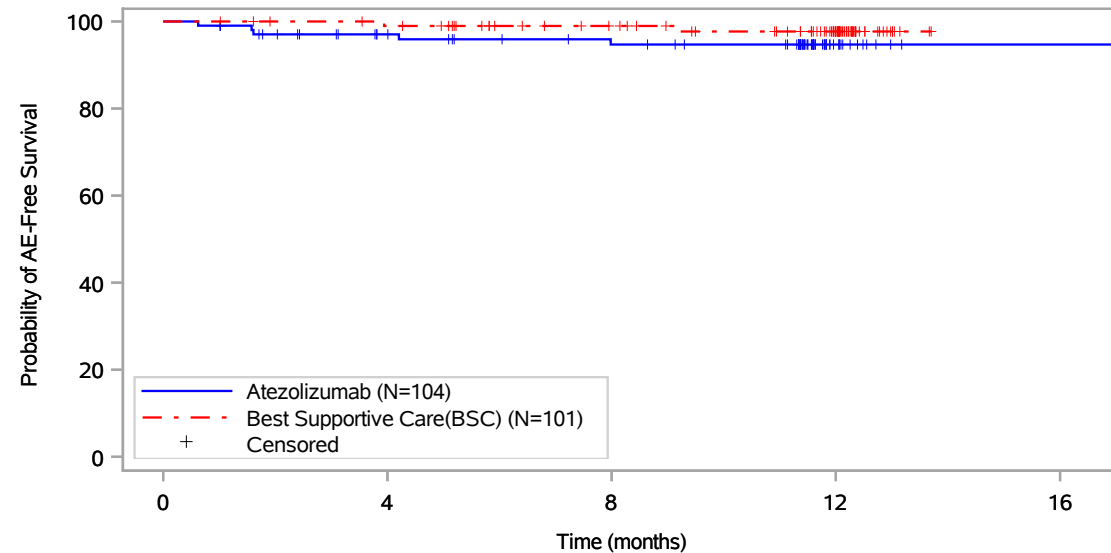
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Dizziness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	86	98
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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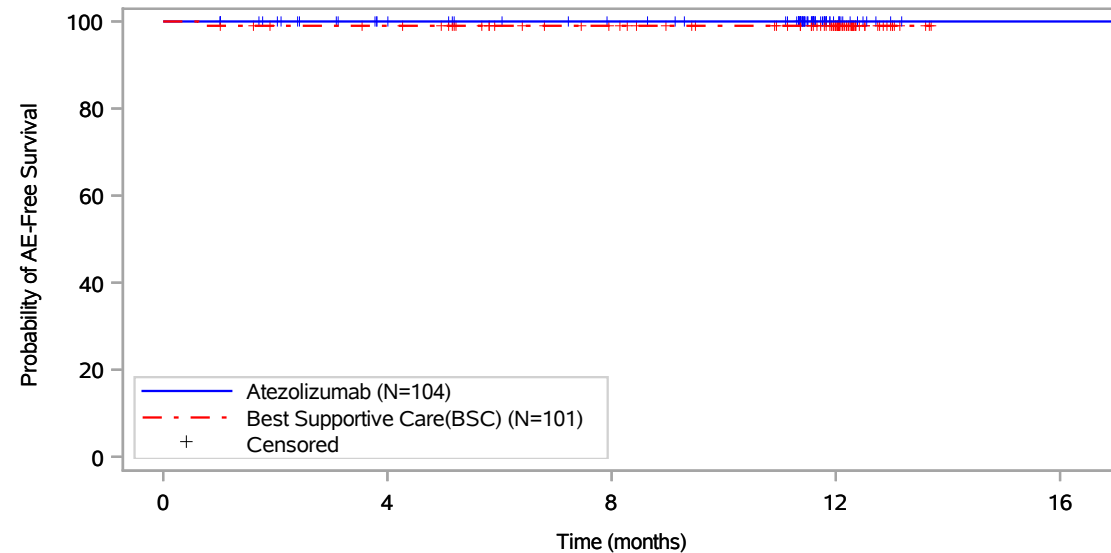
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Dysaesthesia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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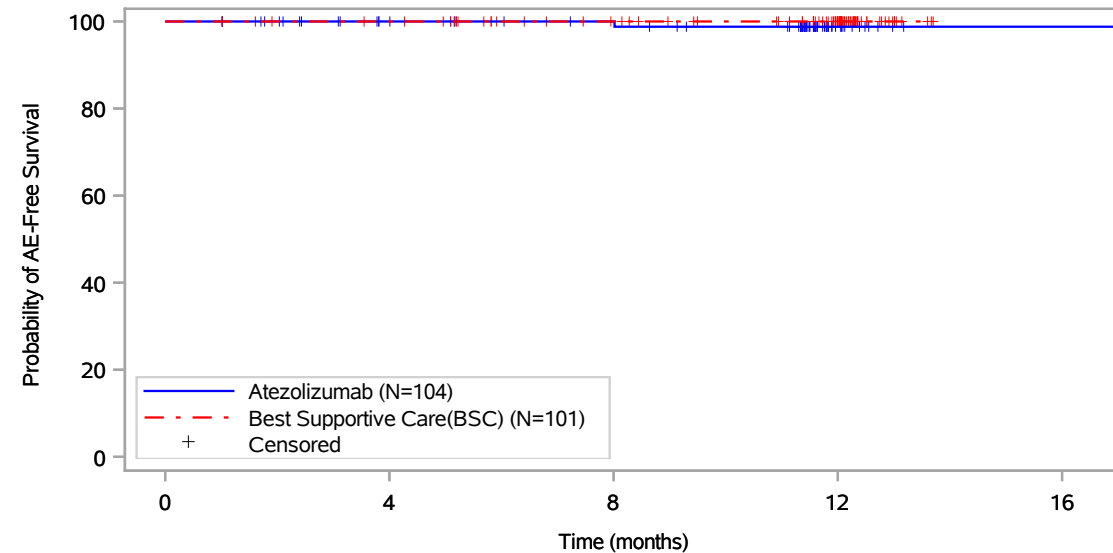
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Encephalopathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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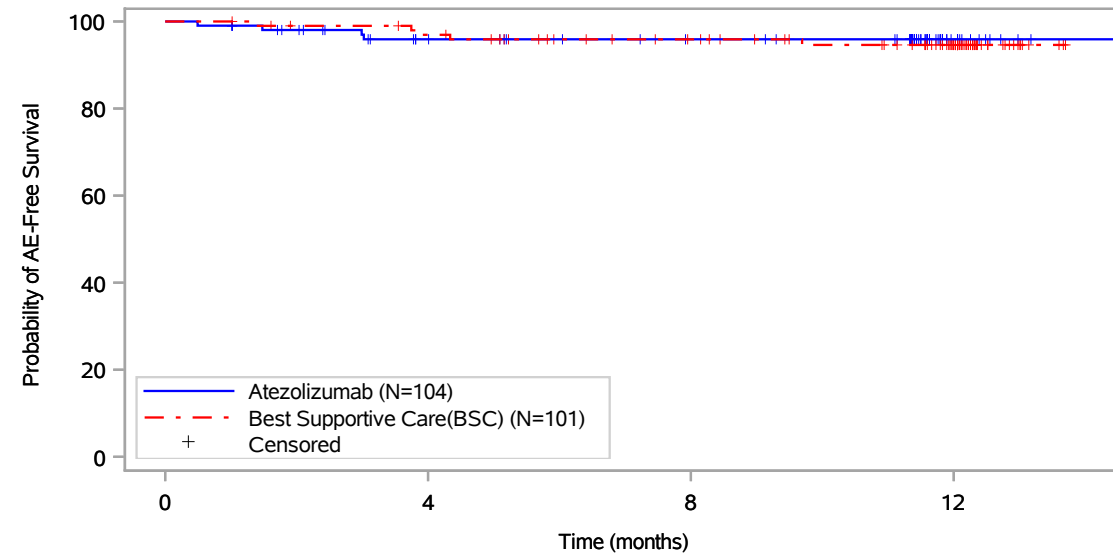
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Headache



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	85	78	13
Best Supportive Care(BSC) (N=101)	101	94	81	53
Patients censored				
Atezolizumab (N=104)	0	15	22	87
Best Supportive Care(BSC) (N=101)	0	4	16	43

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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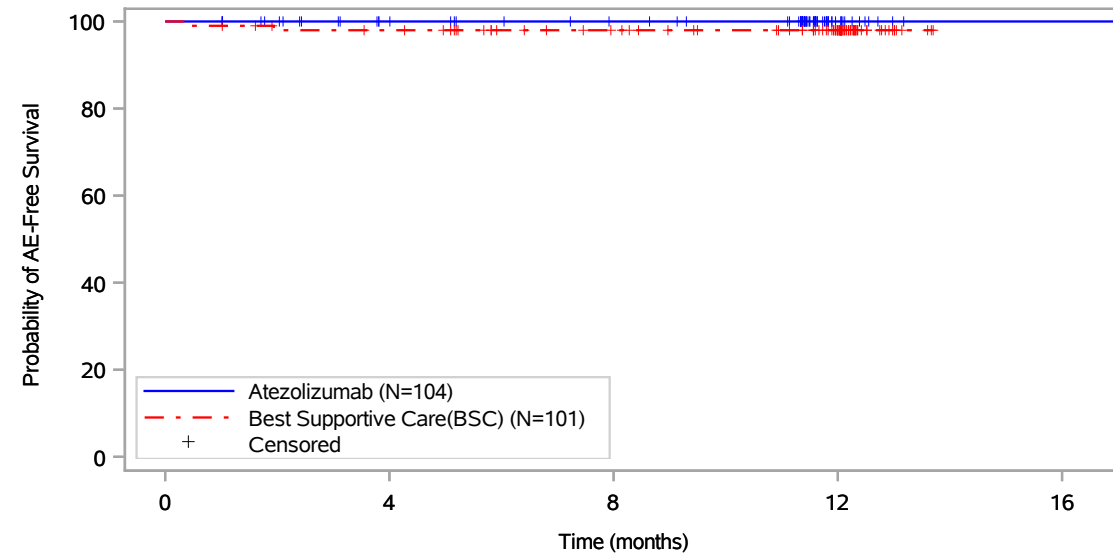
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Hypoaesthesia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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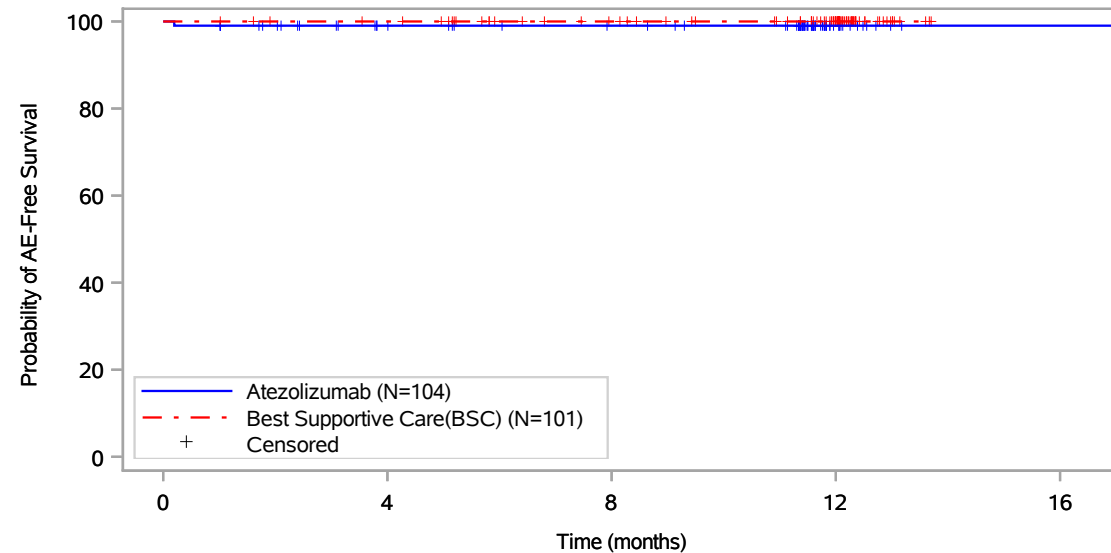
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Lethargy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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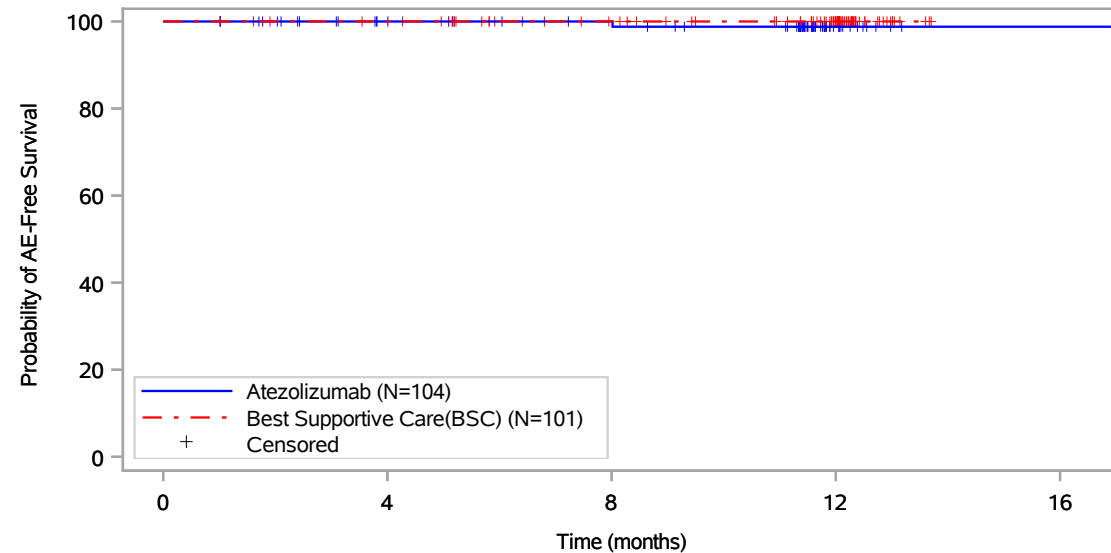
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Loss of consciousness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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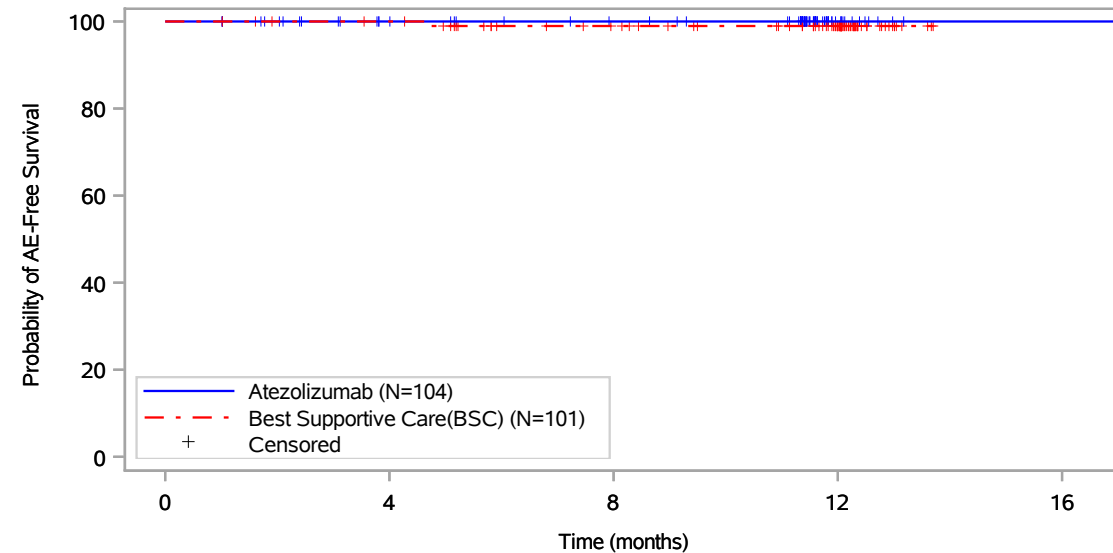
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Memory impairment



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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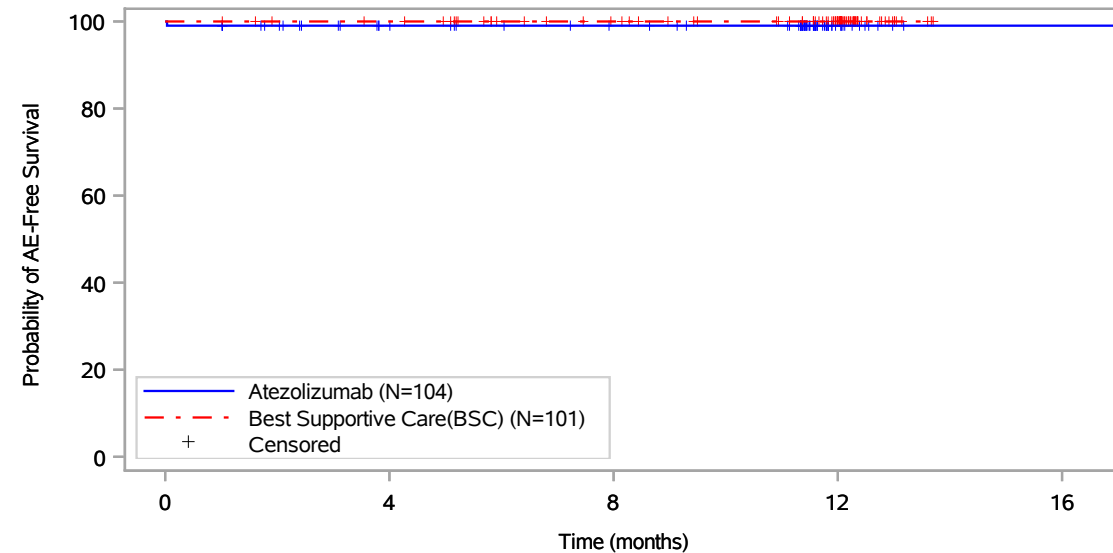
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Migraine



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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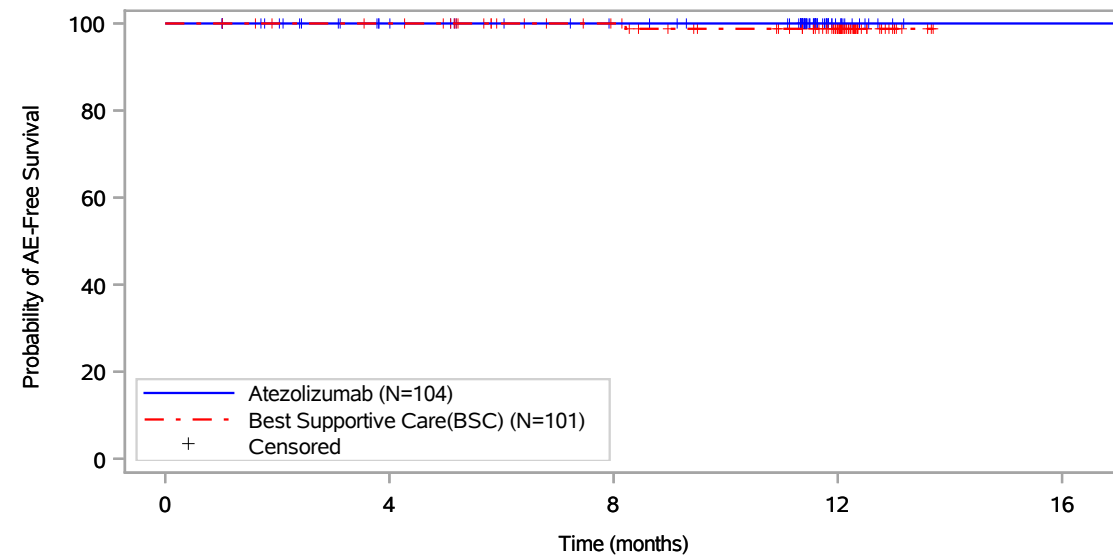
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Myelopathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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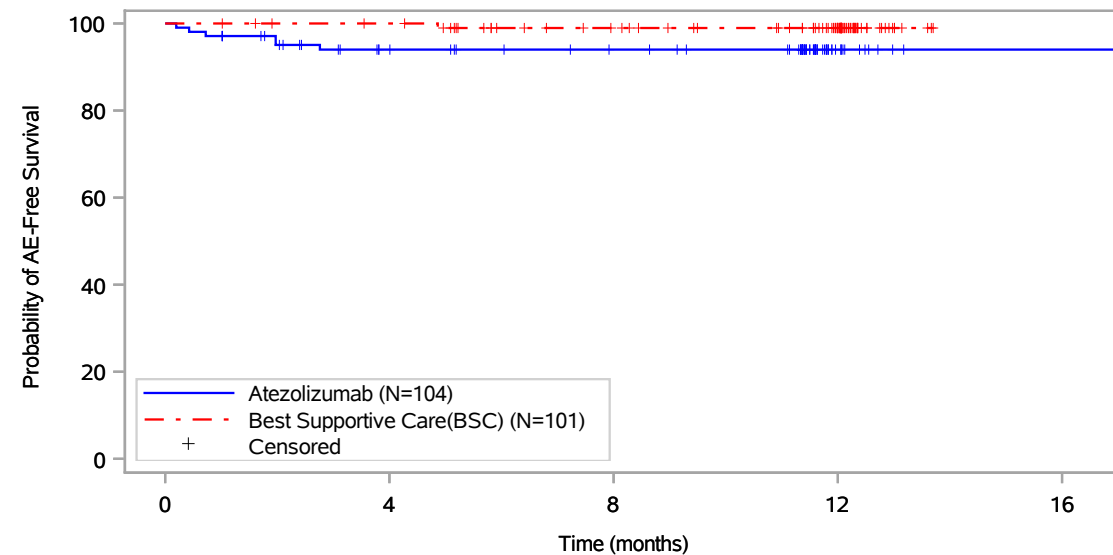
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Neuropathy peripheral



Patients at risk					
Atezolizumab (N=104)	104	83	76	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	86	97
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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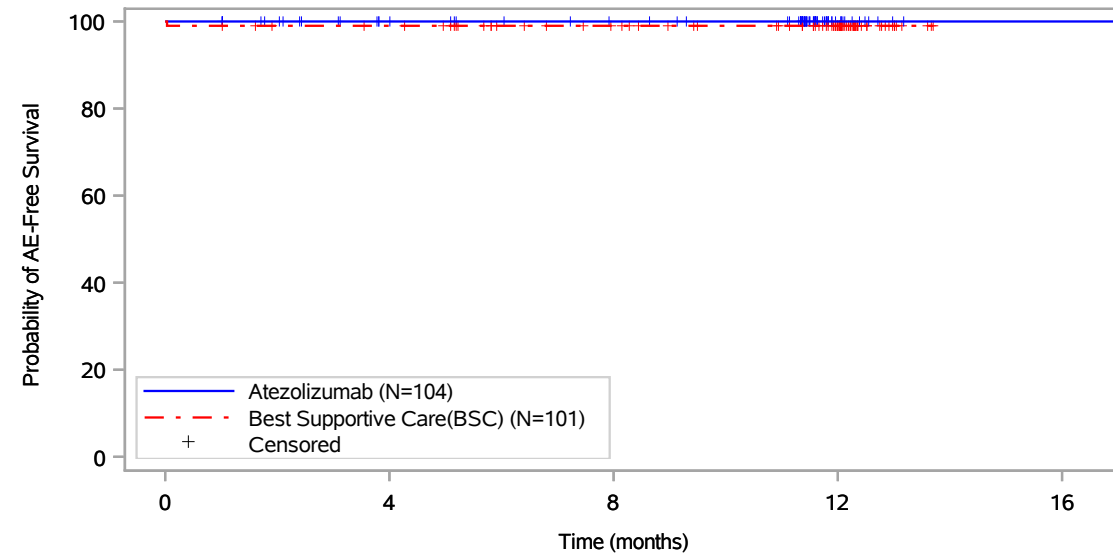
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Neurotoxicity



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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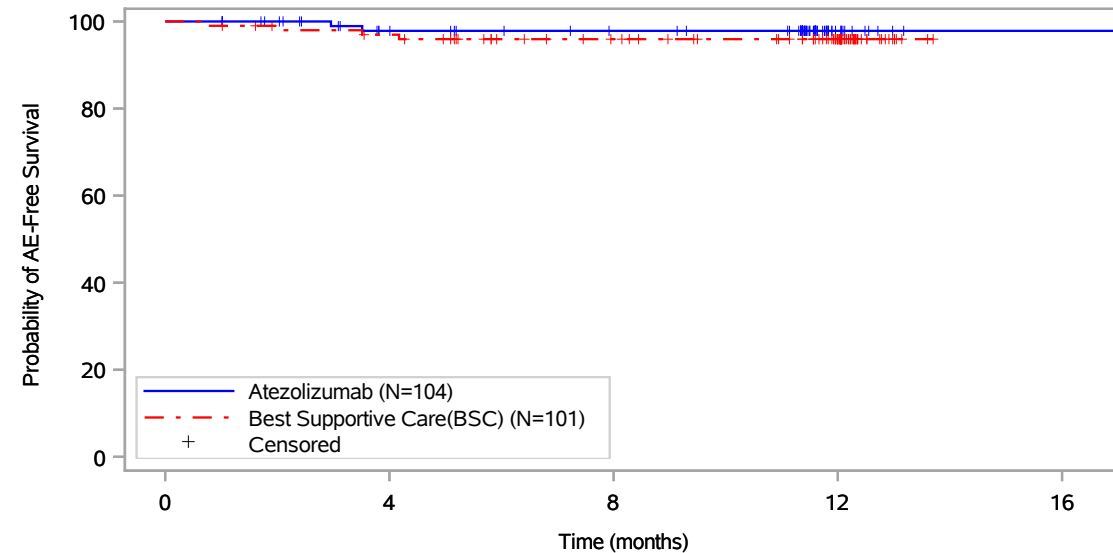
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Paraesthesia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	80	12	1
Best Supportive Care(BSC) (N=101)	101	94	79	51	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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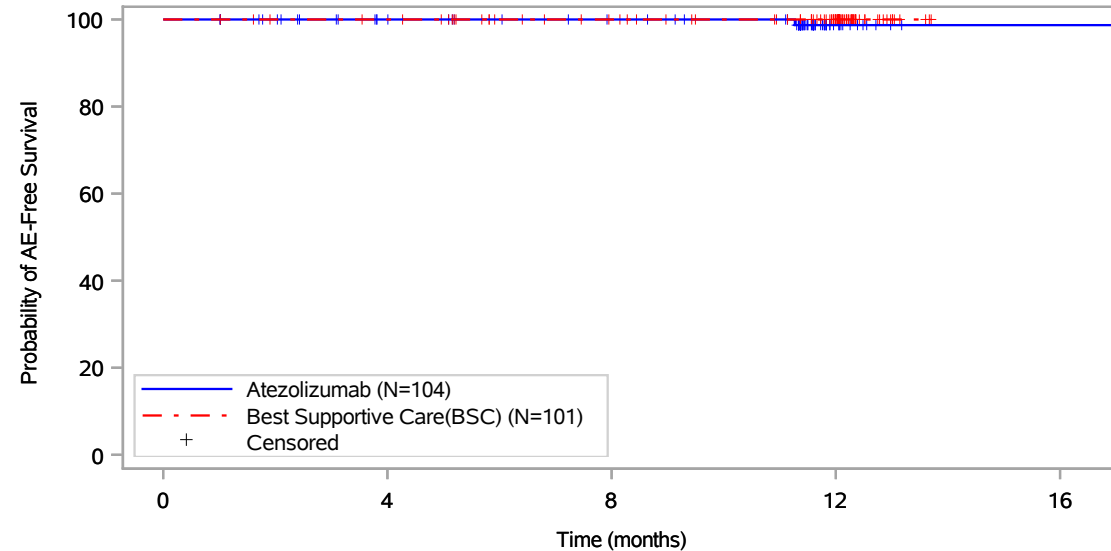
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Parosmia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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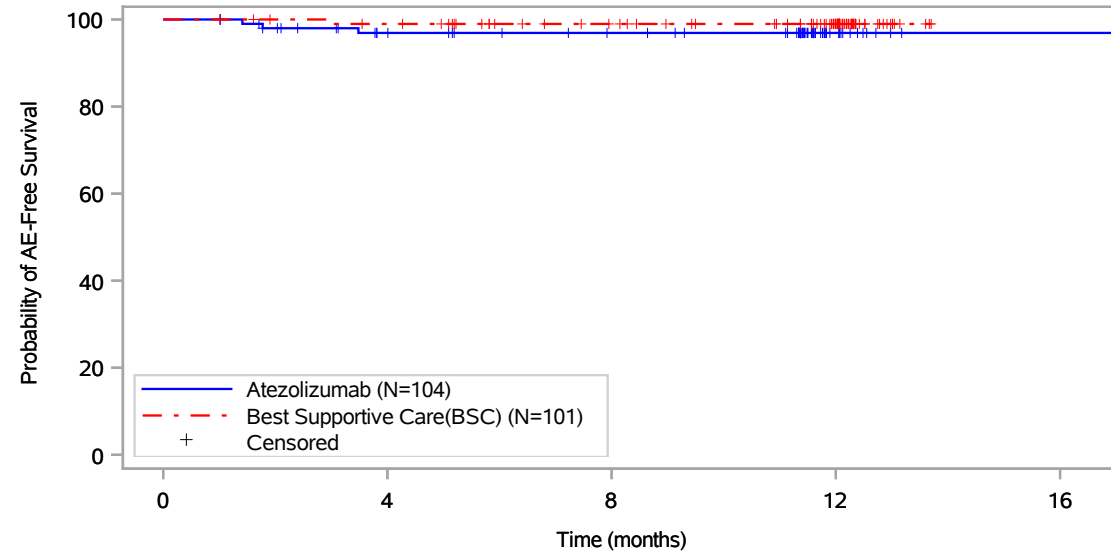
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk					
Atezolizumab (N=104)	104	87	80	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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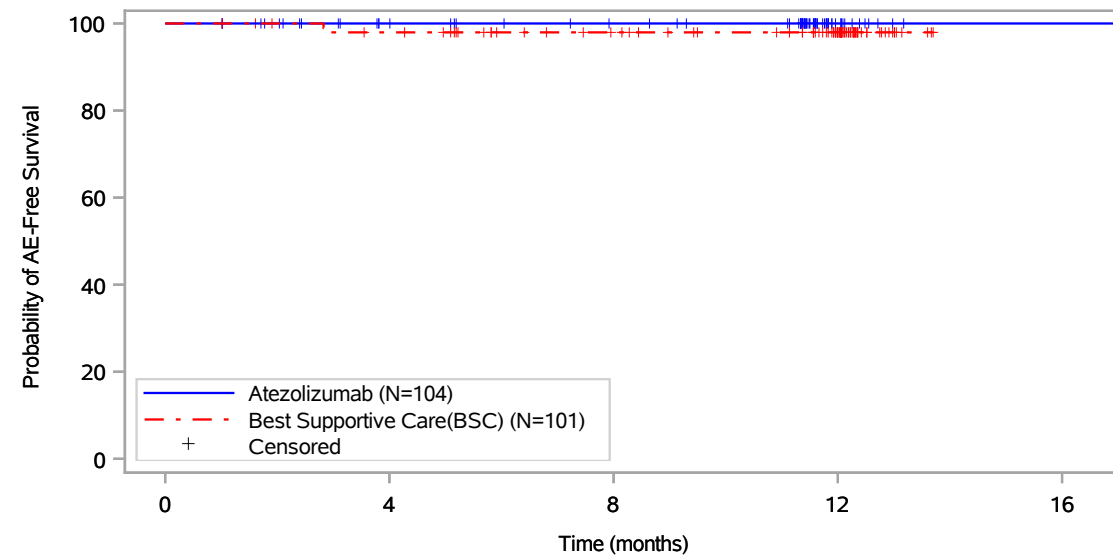
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Polyneuropathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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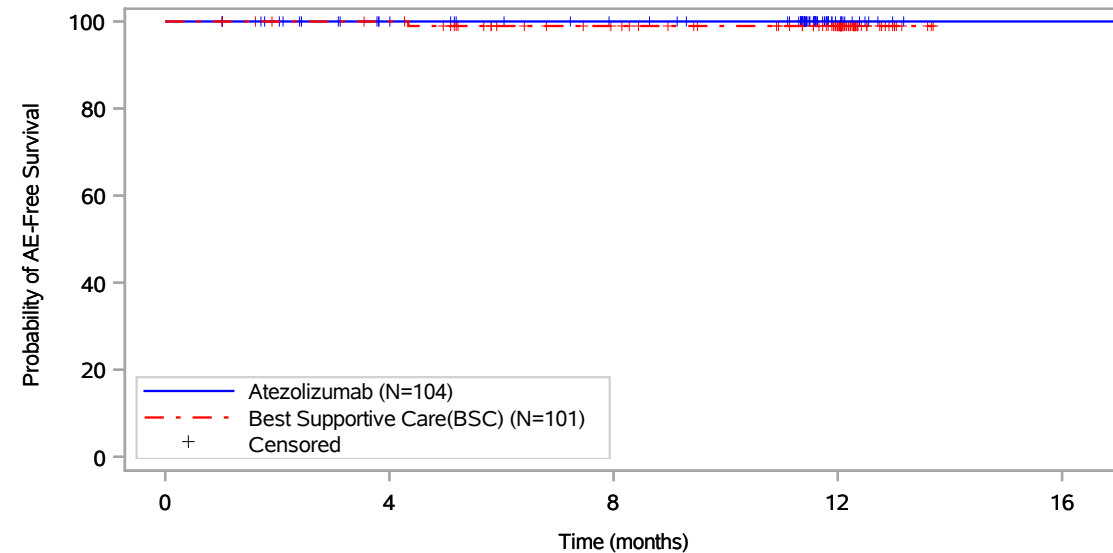
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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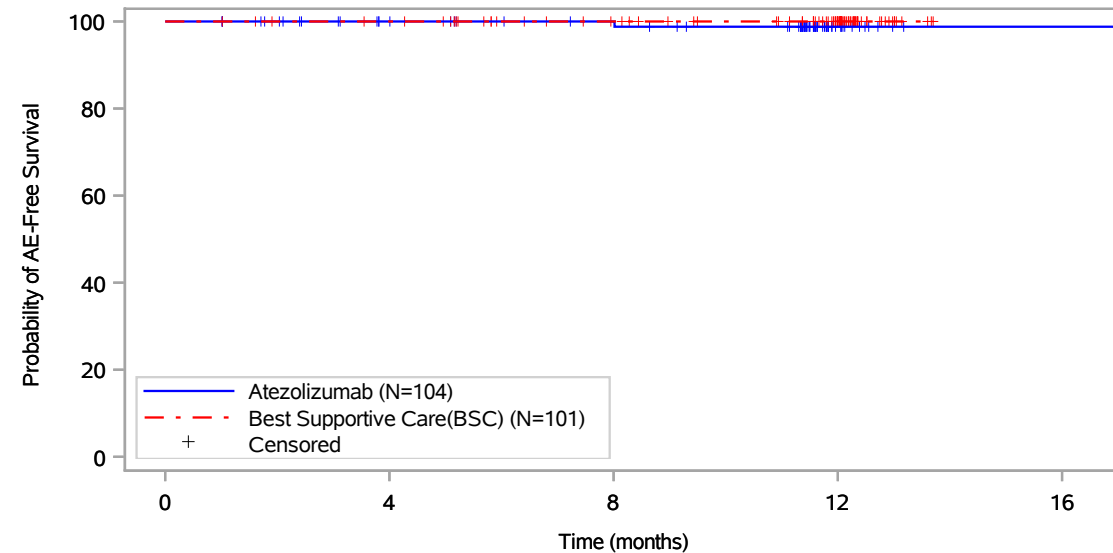
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Seizure



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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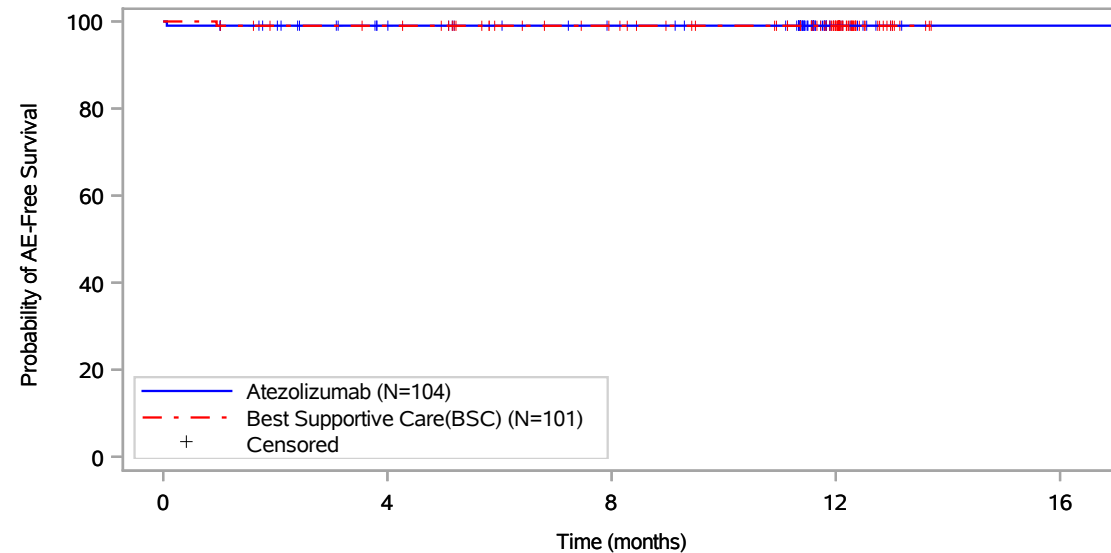
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Somnolence



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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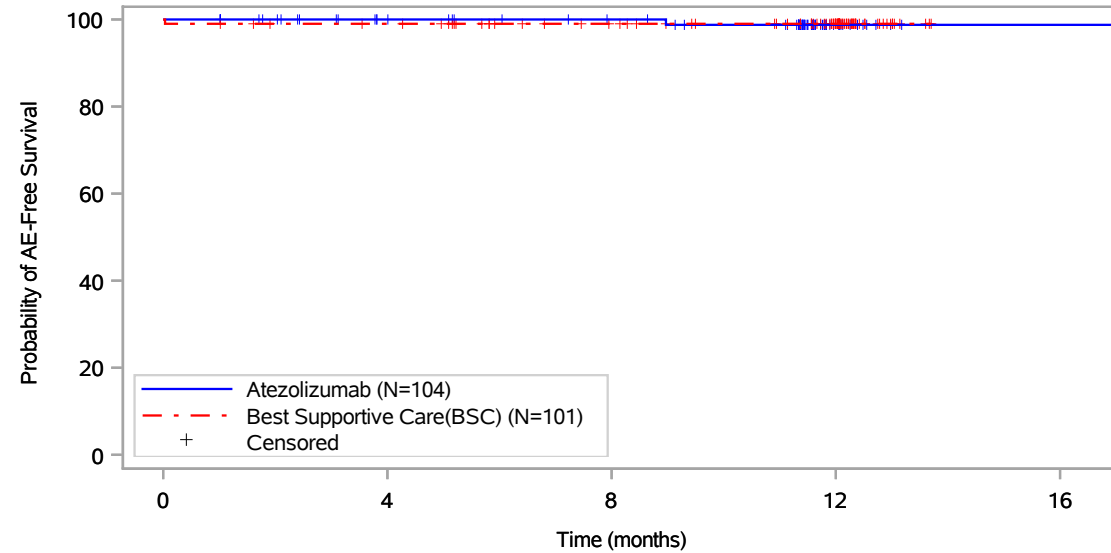
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Syncope



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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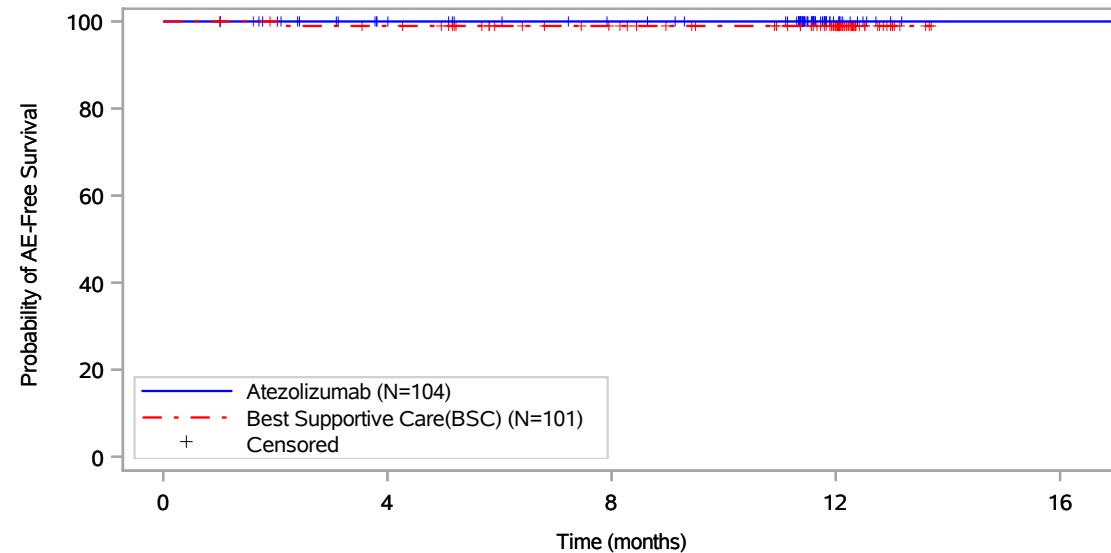
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Tension headache



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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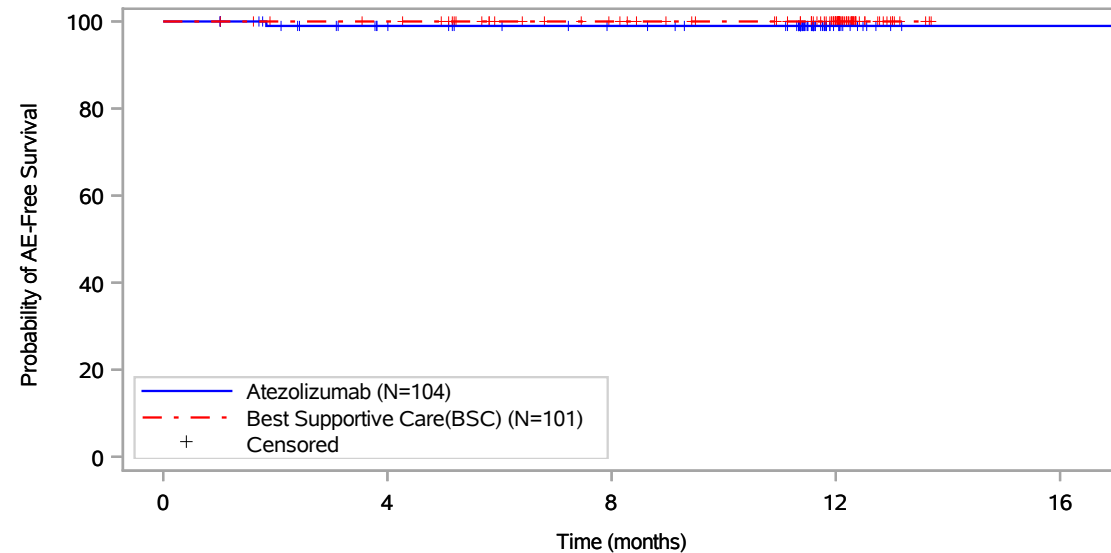
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Transient ischaemic attack



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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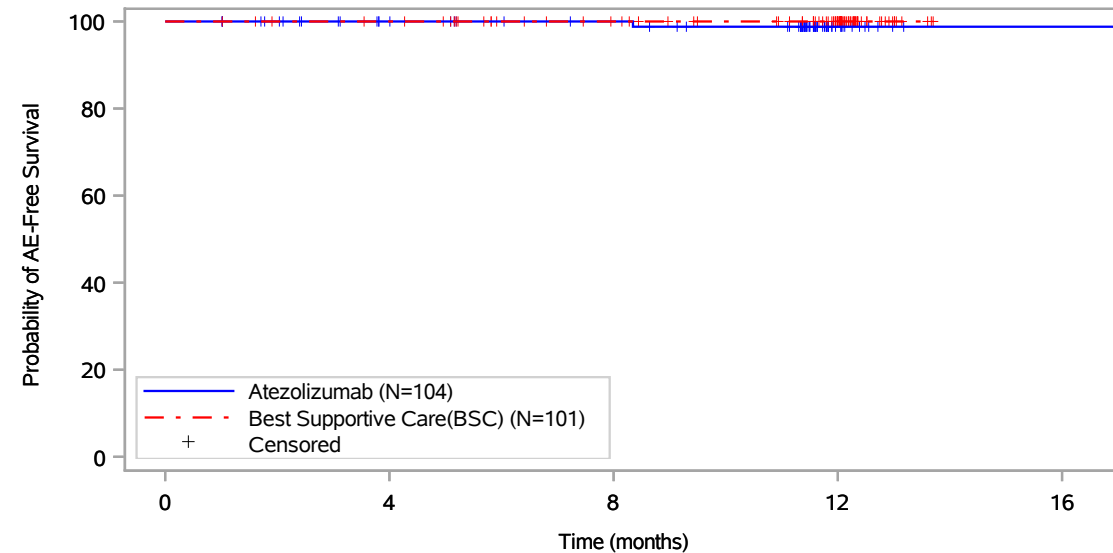
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Upper motor neurone lesion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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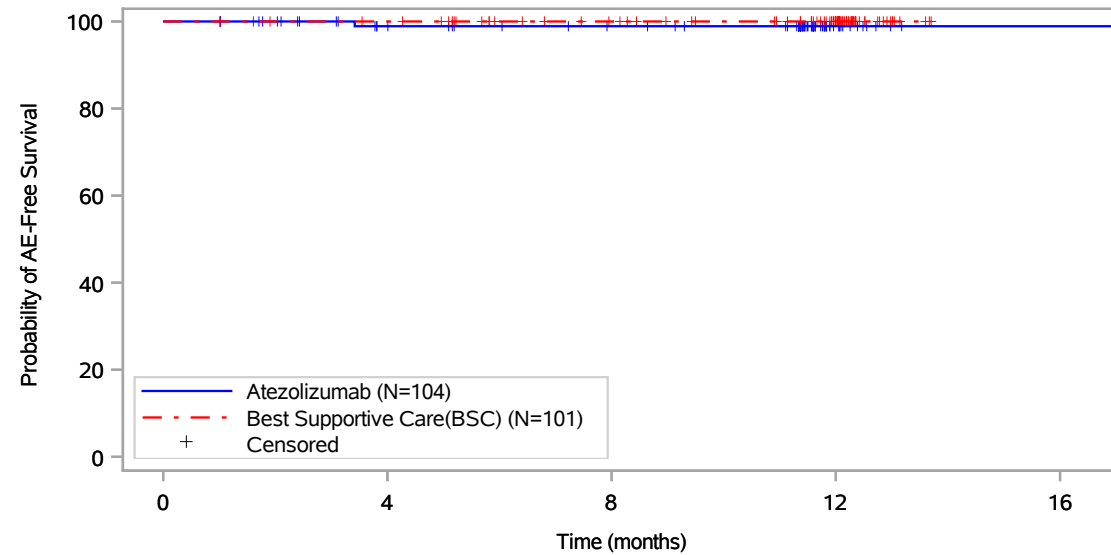
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Nervous system disorders, Vocal cord paralysis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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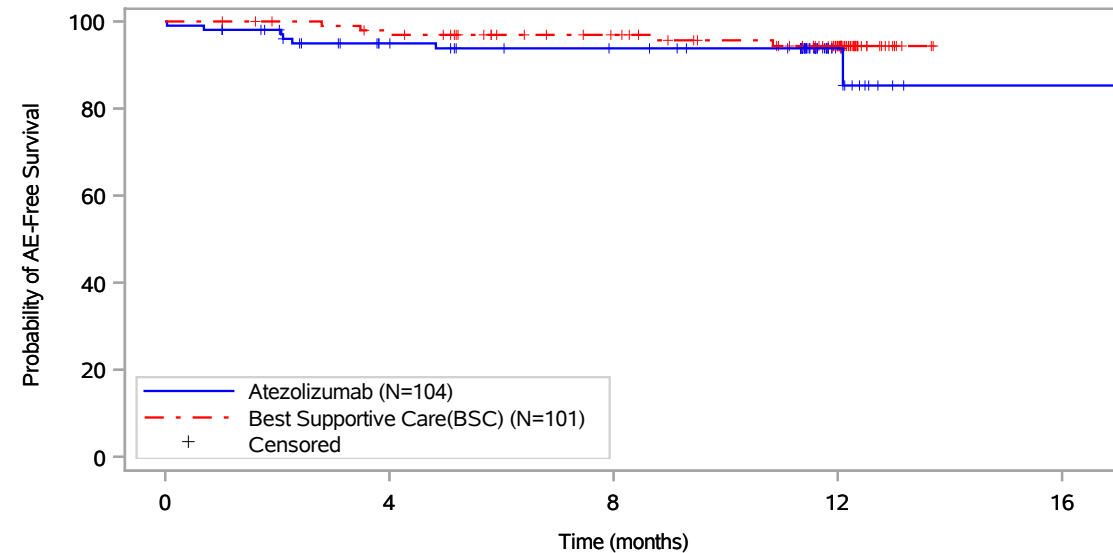
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	84	77	13	1
Best Supportive Care(BSC) (N=101)	101	94	80	51	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	85	96
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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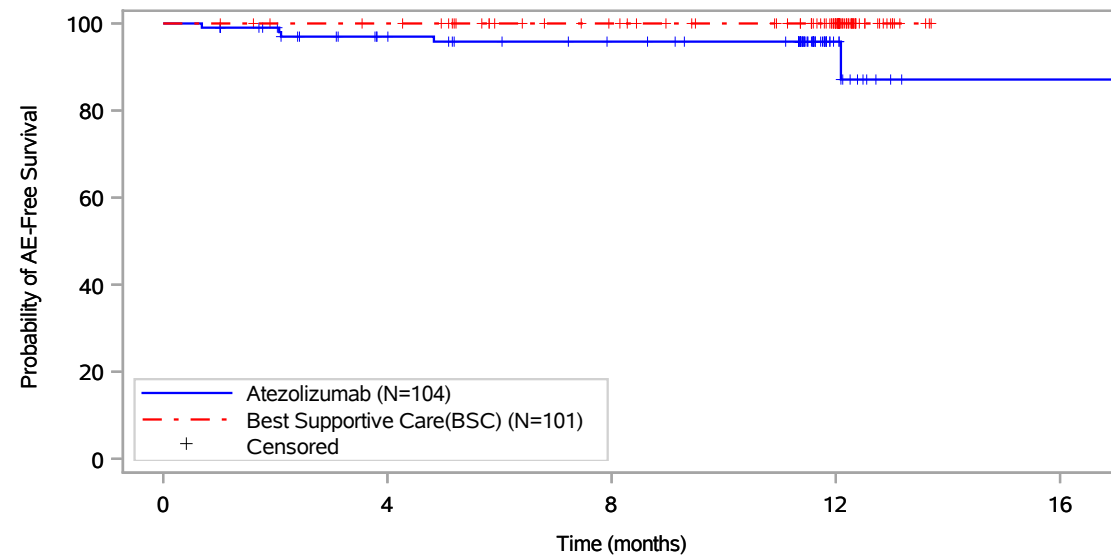
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Anxiety



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	78	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	98
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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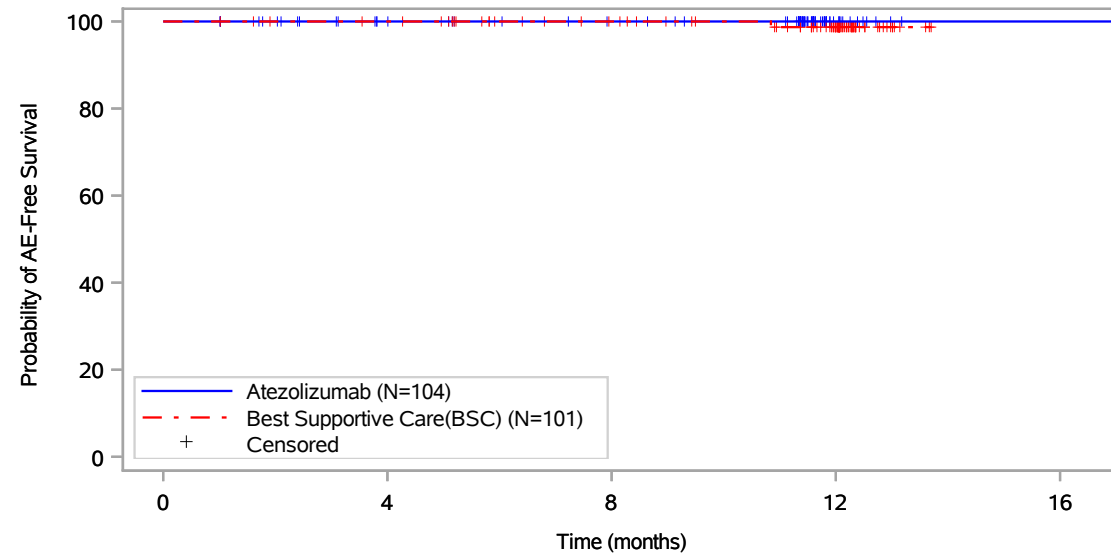
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Depressed mood



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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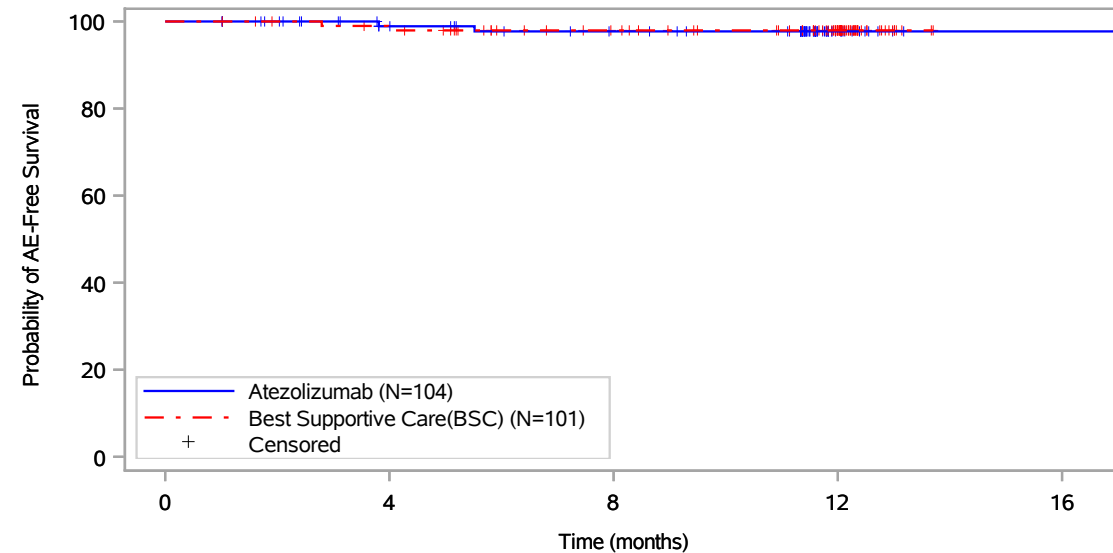
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Depression



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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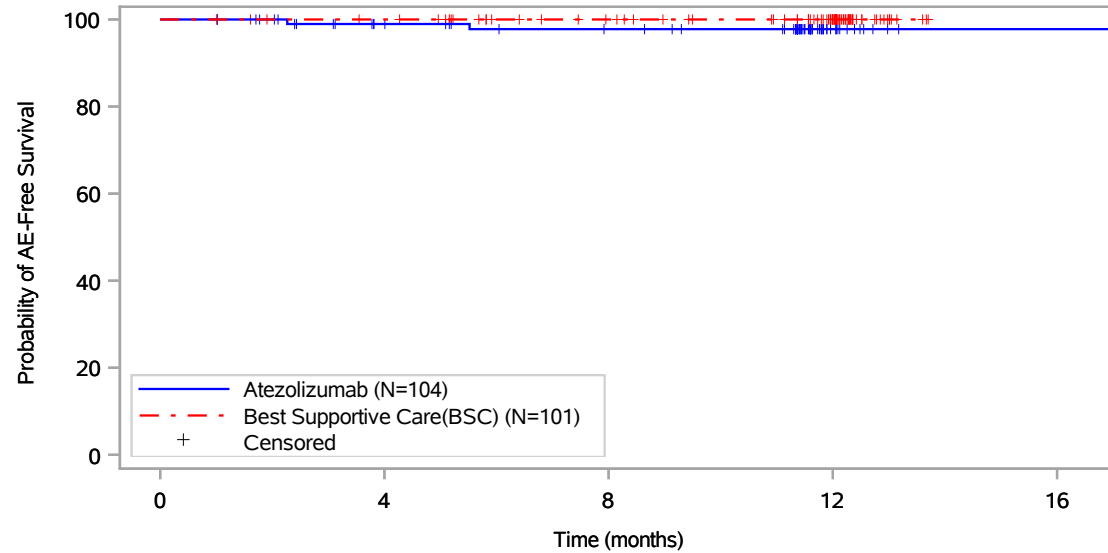
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Insomnia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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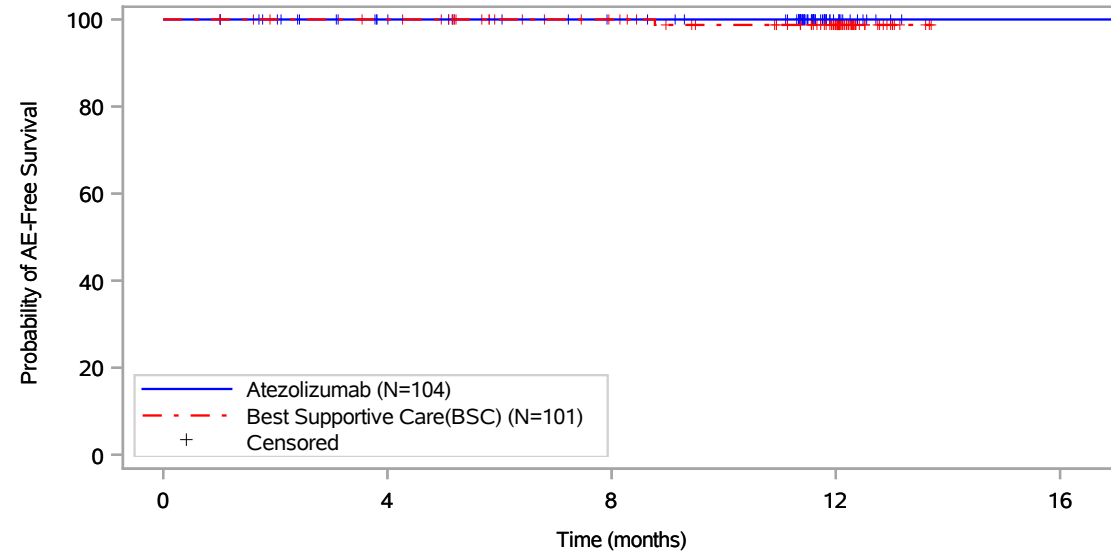
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Mental status changes



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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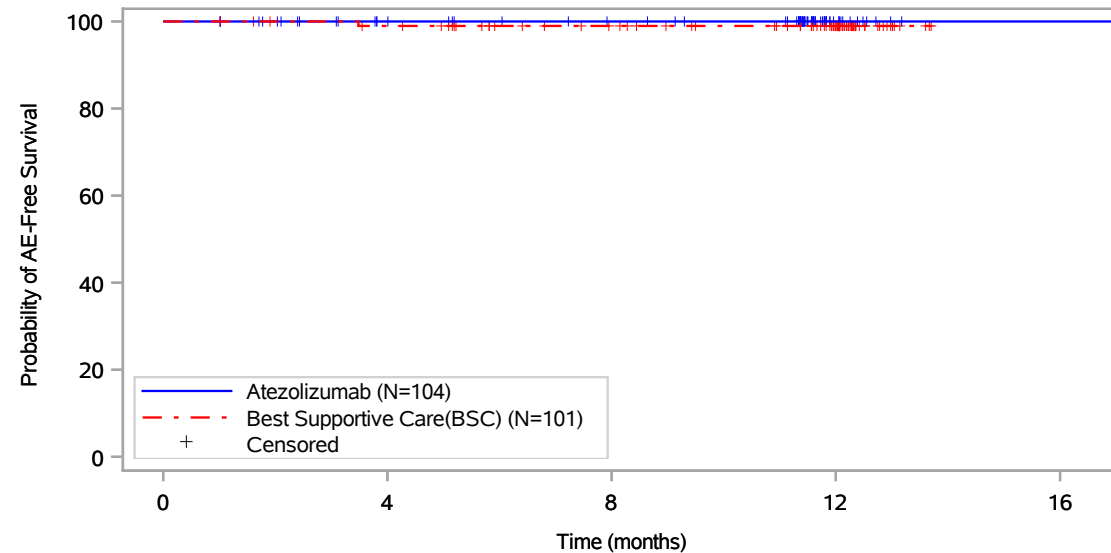
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Psychiatric symptom



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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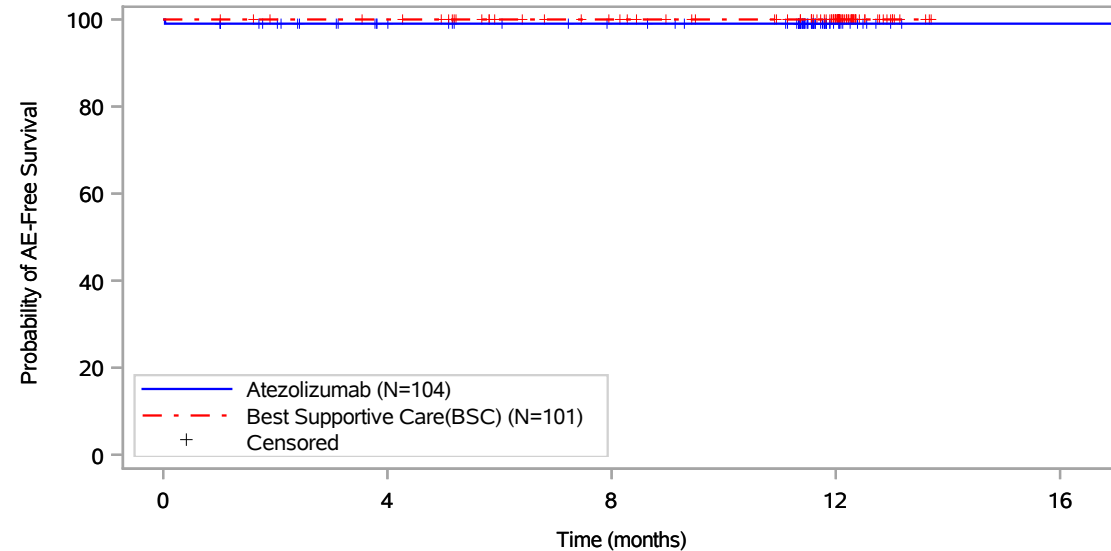
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Psychiatric disorders, Sleep disorder



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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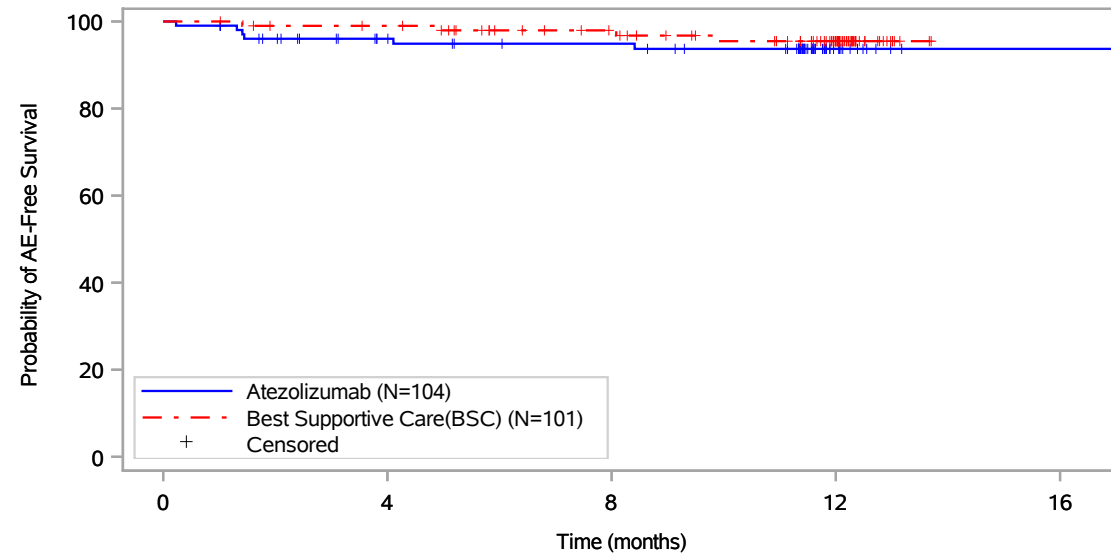
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	85	80	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	19	85	97
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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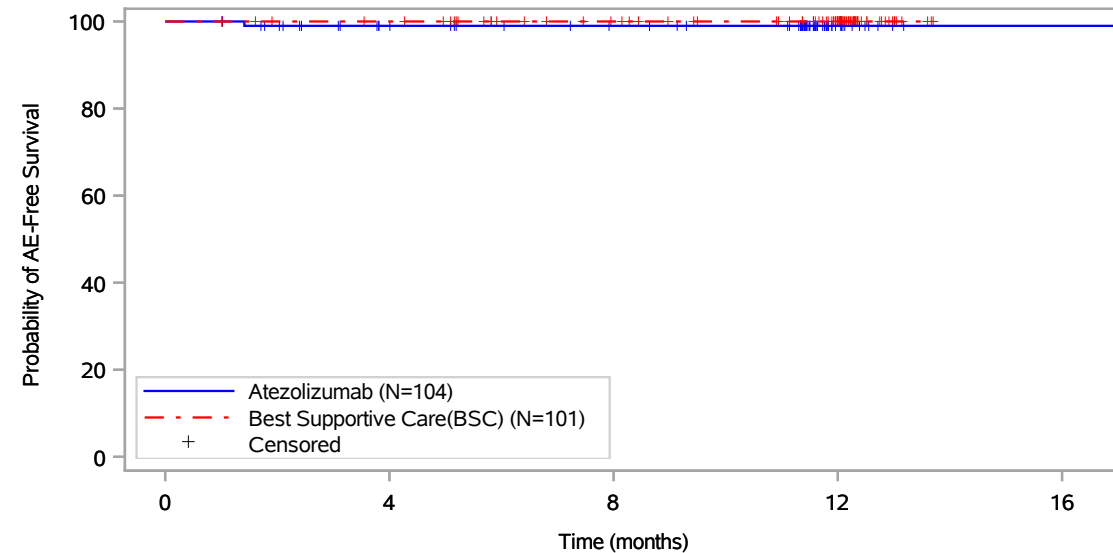
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Acute kidney injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

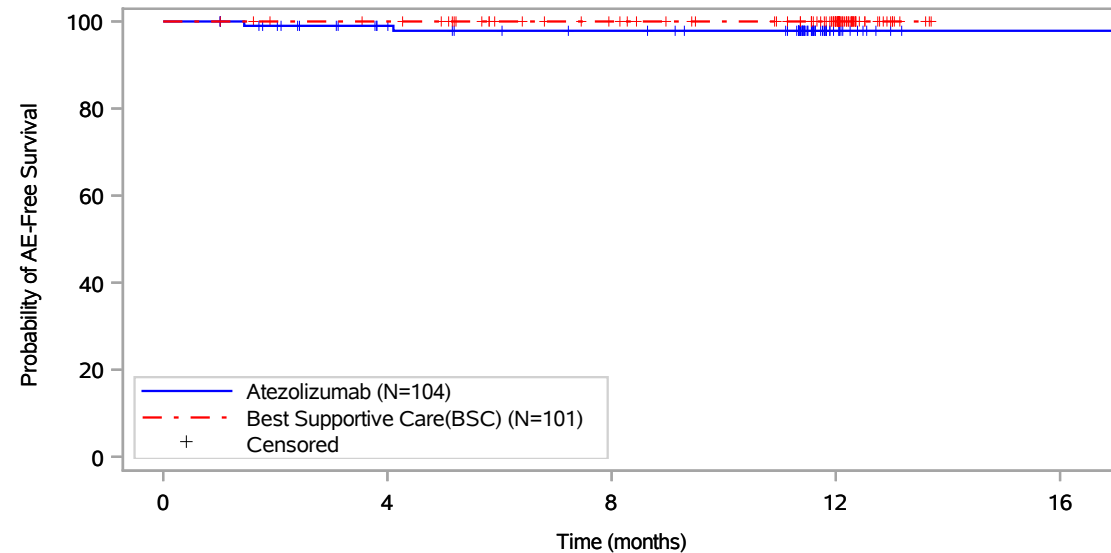
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



Patients at risk					
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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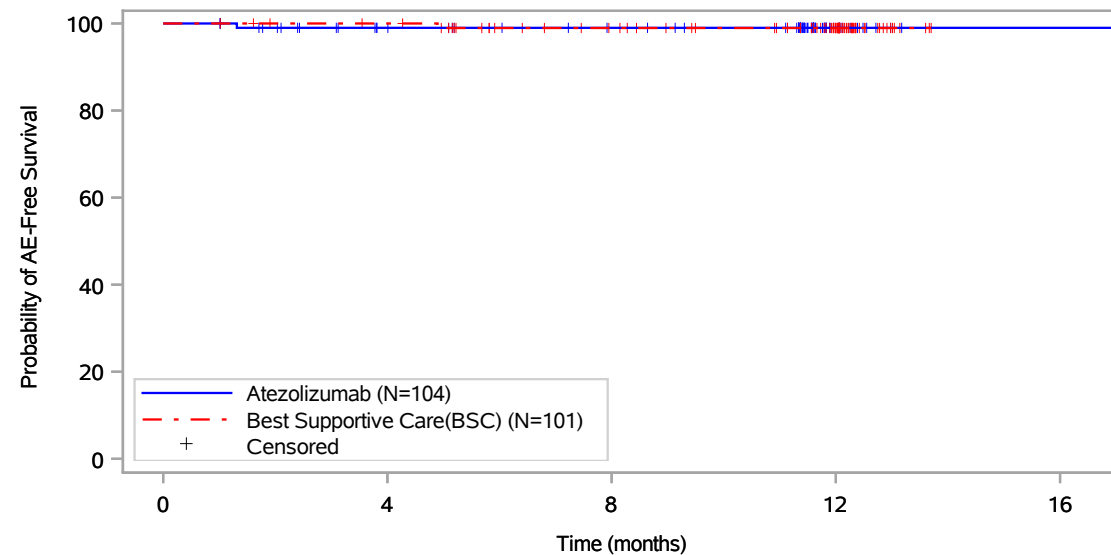
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Dysuria



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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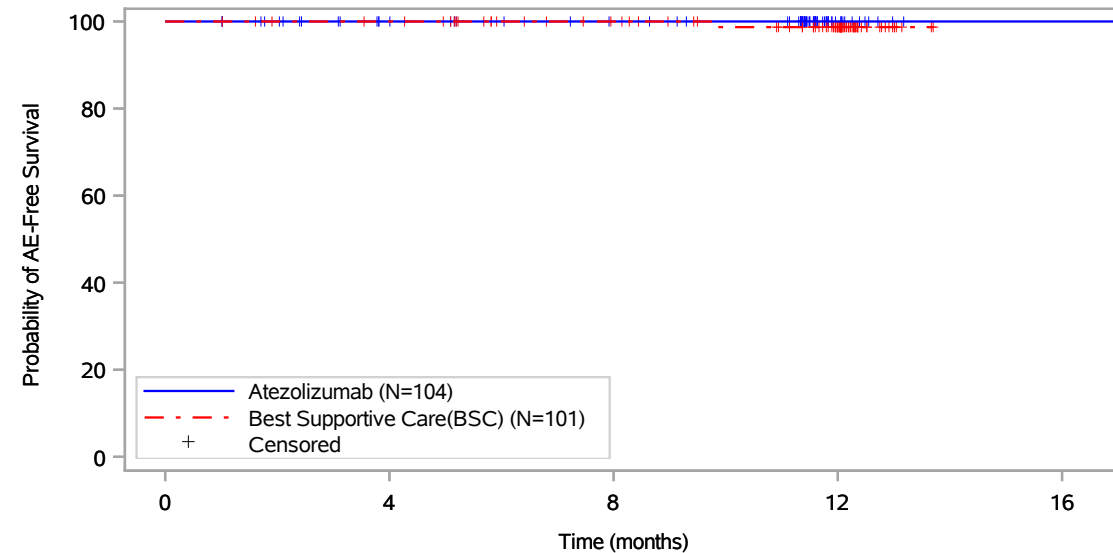
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Lower urinary tract symptoms



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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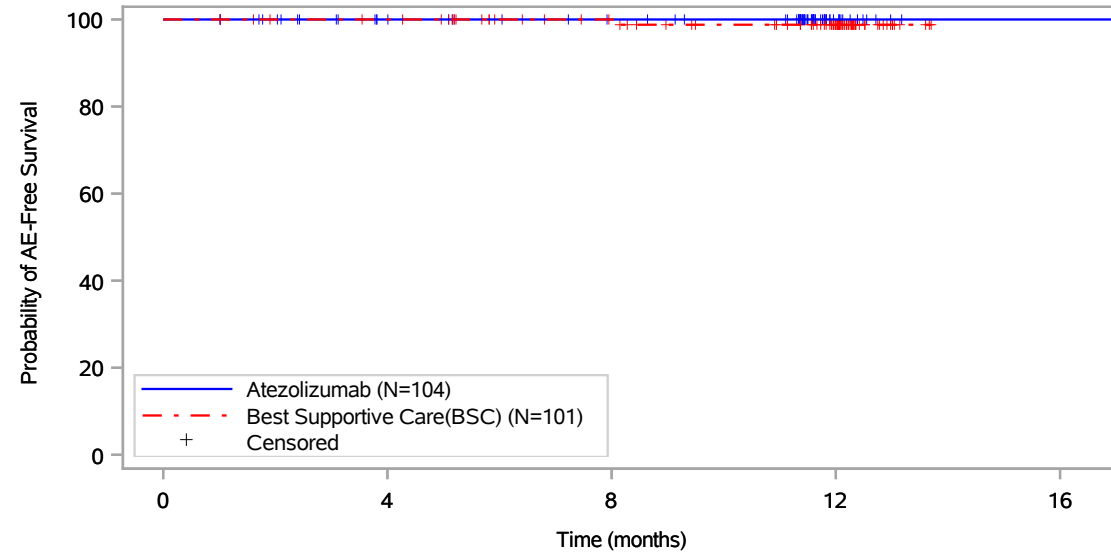
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Micturition disorder



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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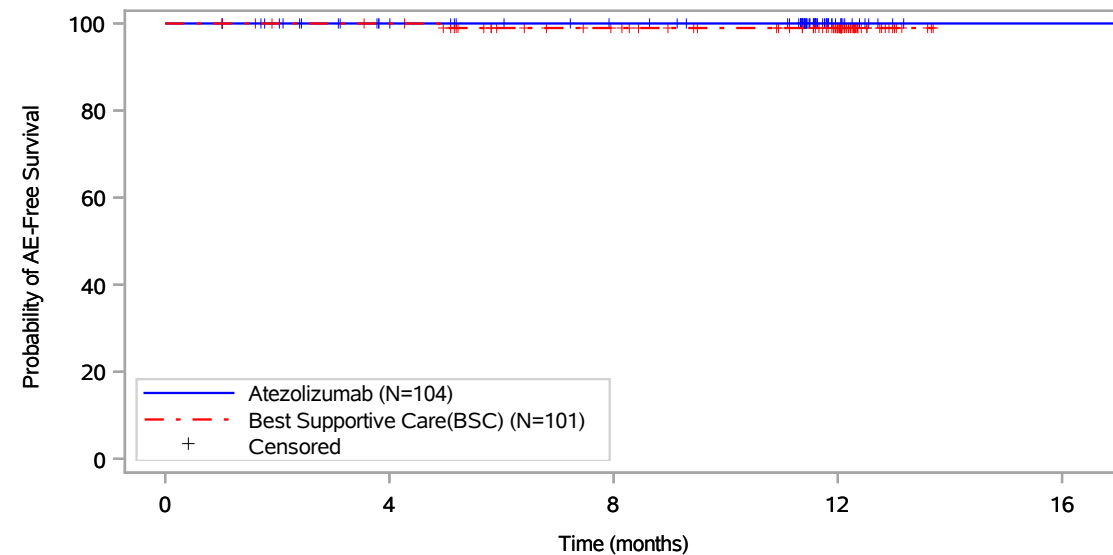
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Pollakiuria



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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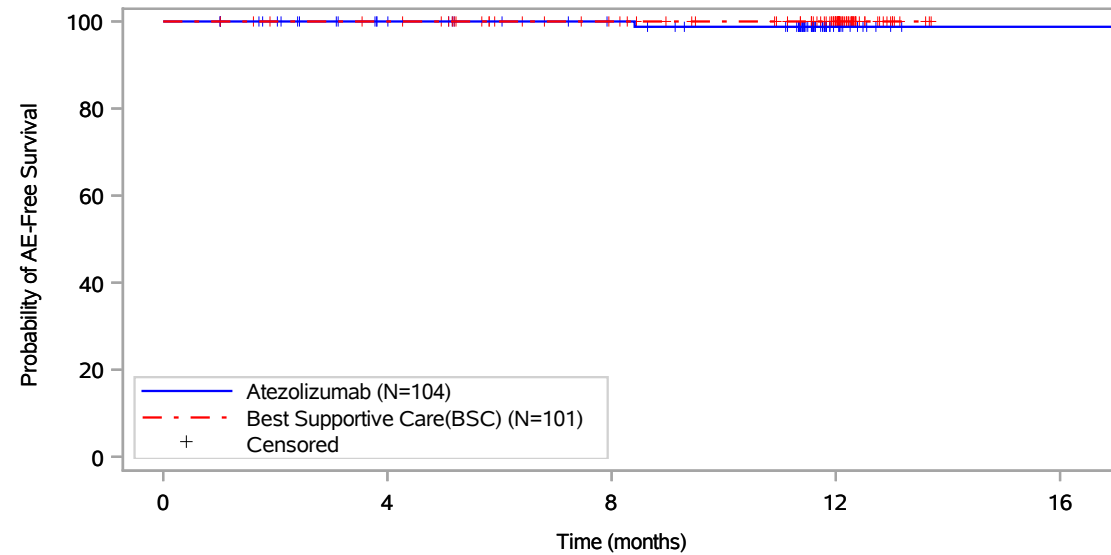
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Proteinuria



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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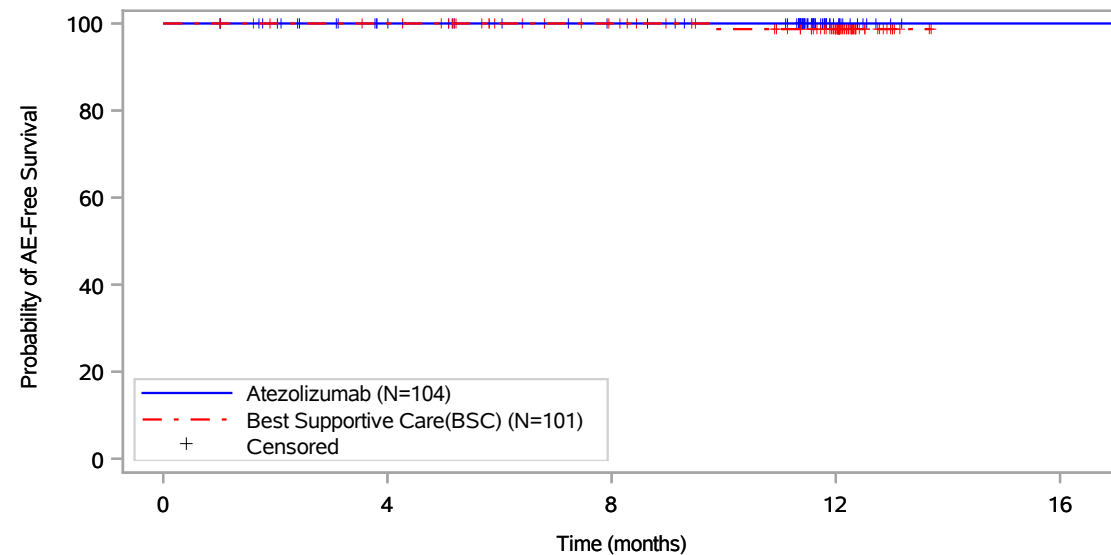
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Renal cyst



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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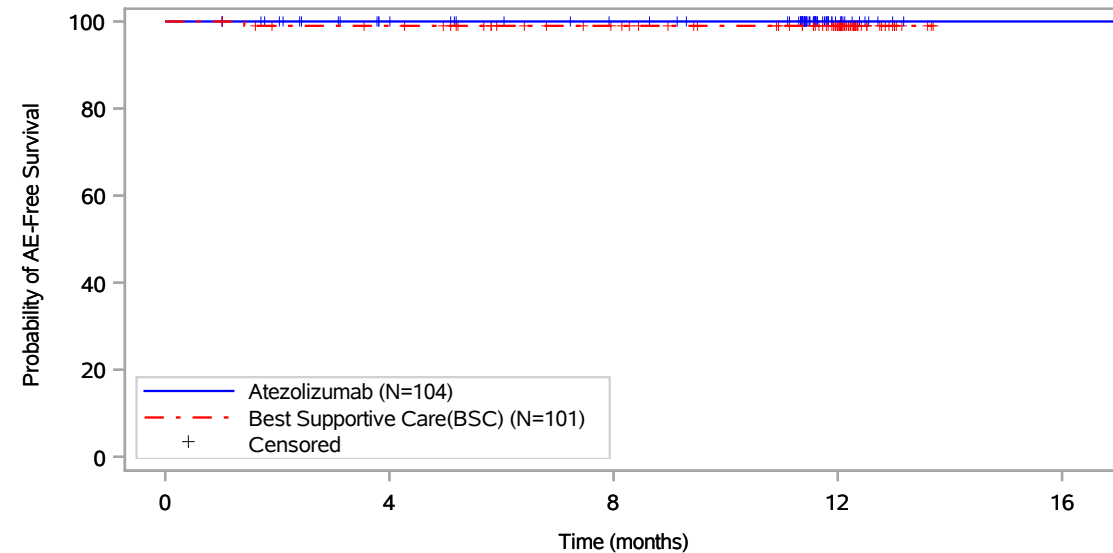
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Renal impairment



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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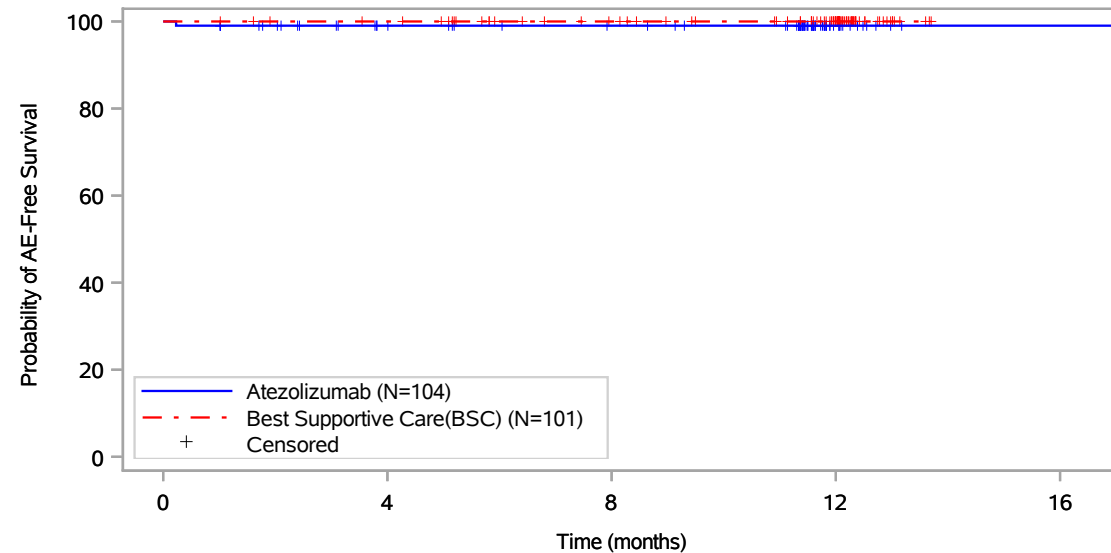
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Renal and urinary disorders, Urinary tract pain



Patients at risk					
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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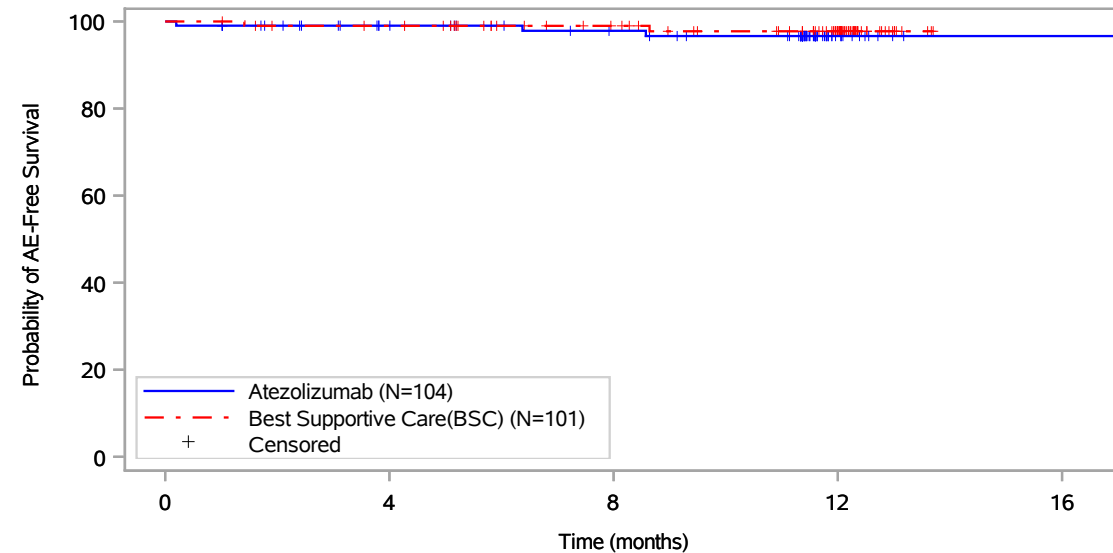
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	89	100
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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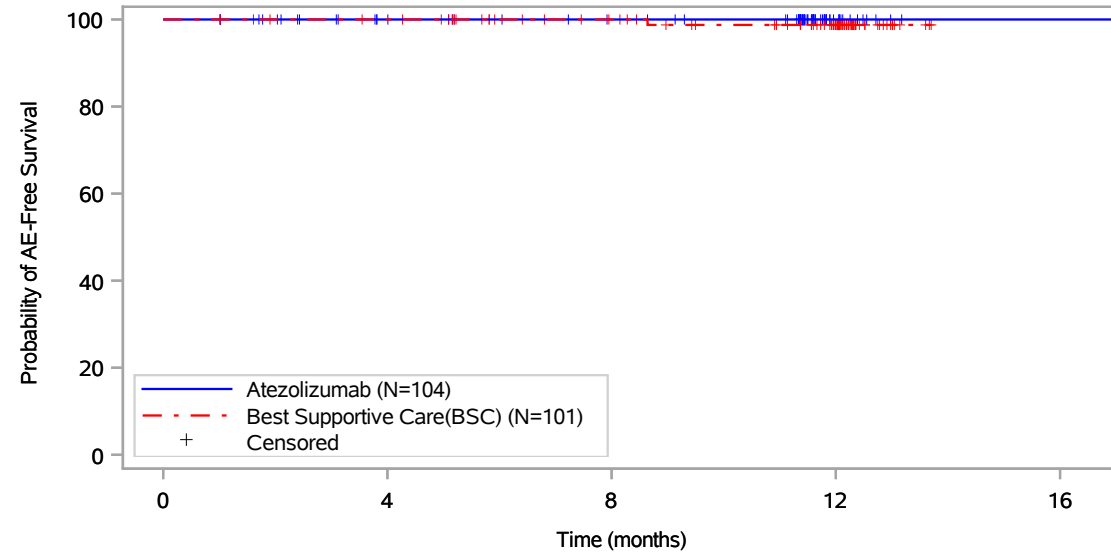
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Balanoposthitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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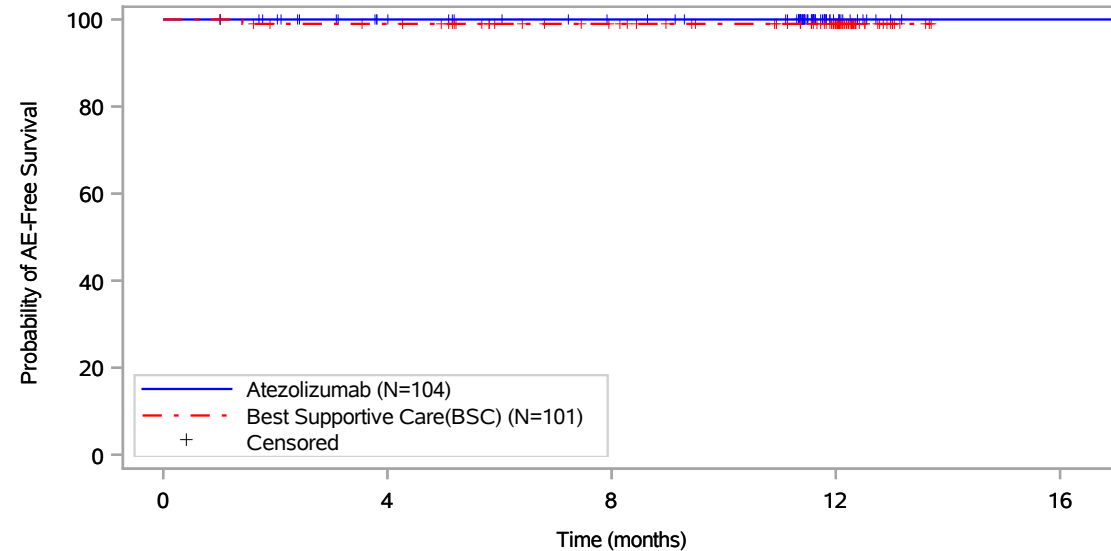
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Breast discharge



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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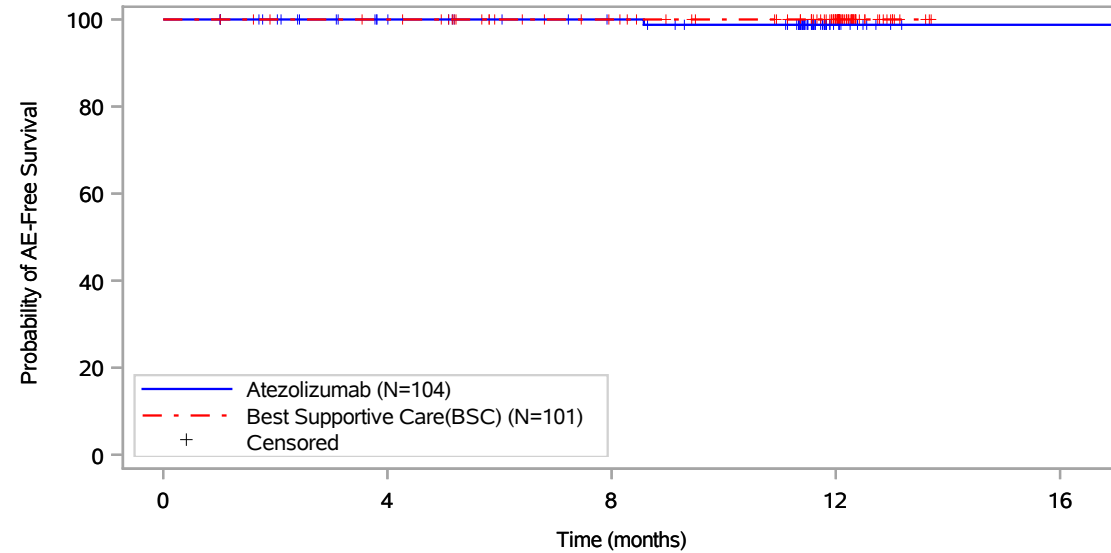
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Breast pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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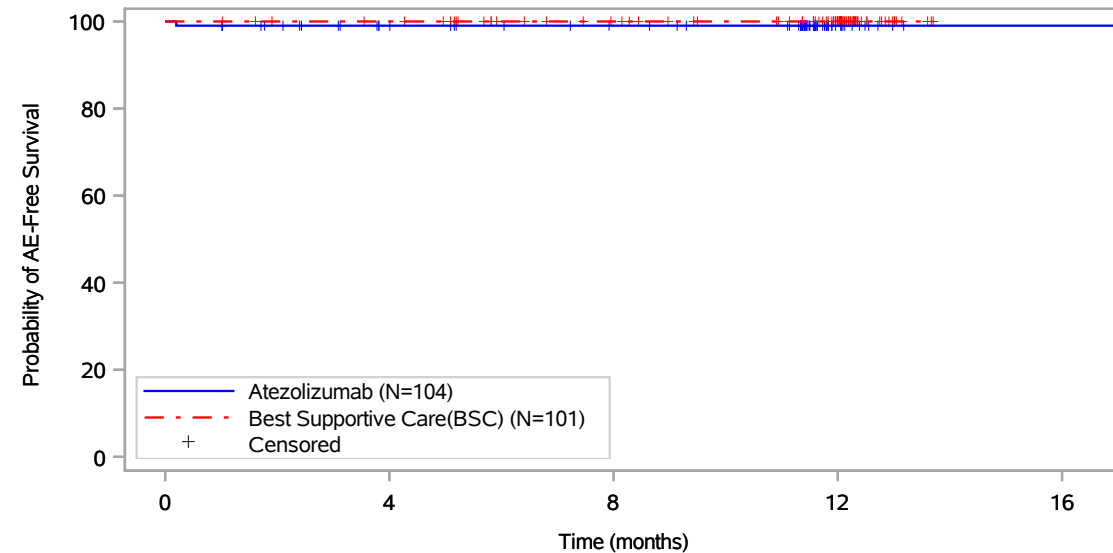
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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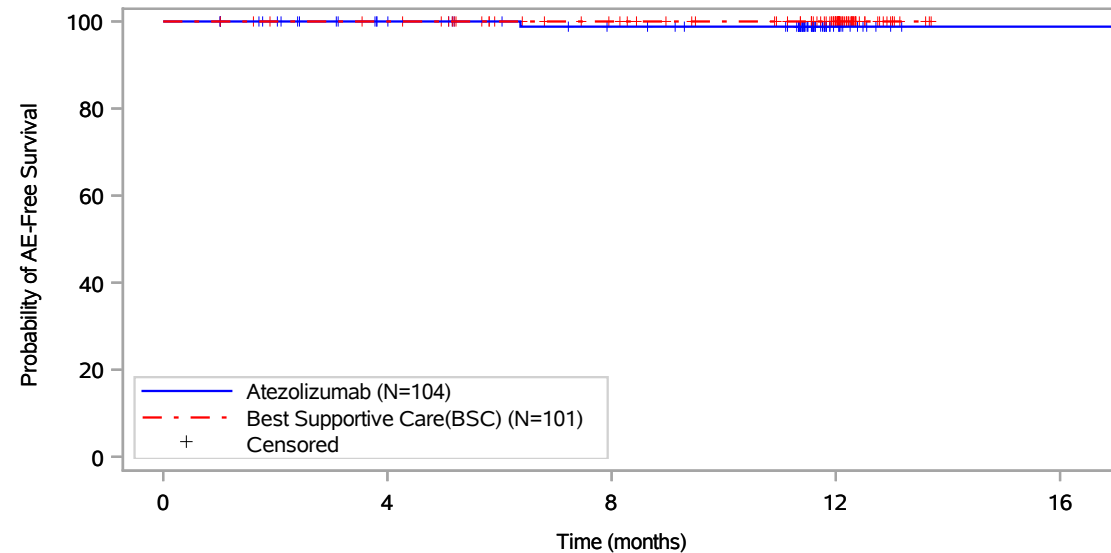
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Gynaecomastia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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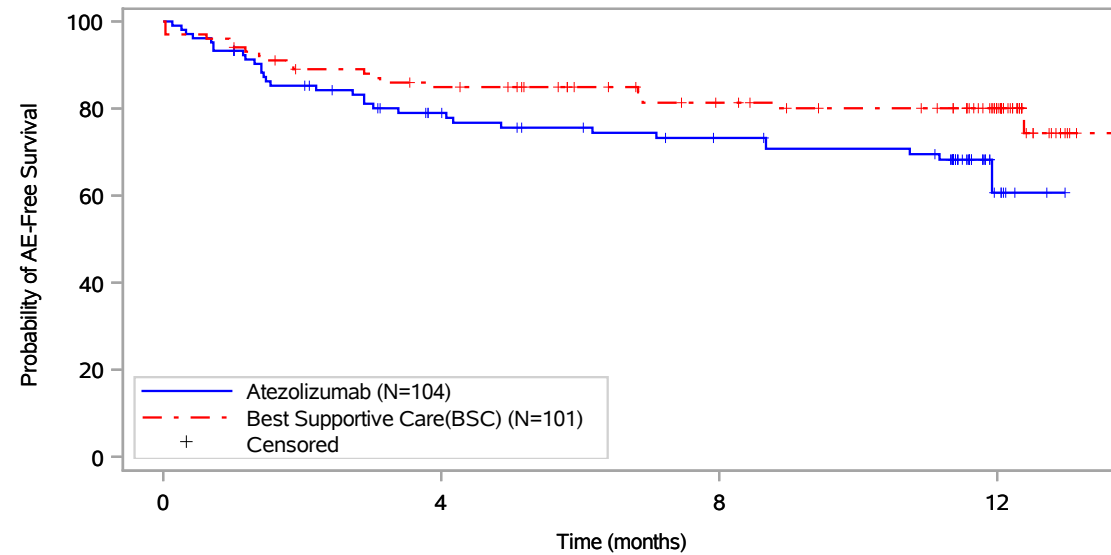
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	71	60	7
Best Supportive Care(BSC) (N=101)	101	82	66	41
Patients censored				
Atezolizumab (N=104)	0	12	18	66
Best Supportive Care(BSC) (N=101)	0	4	17	41

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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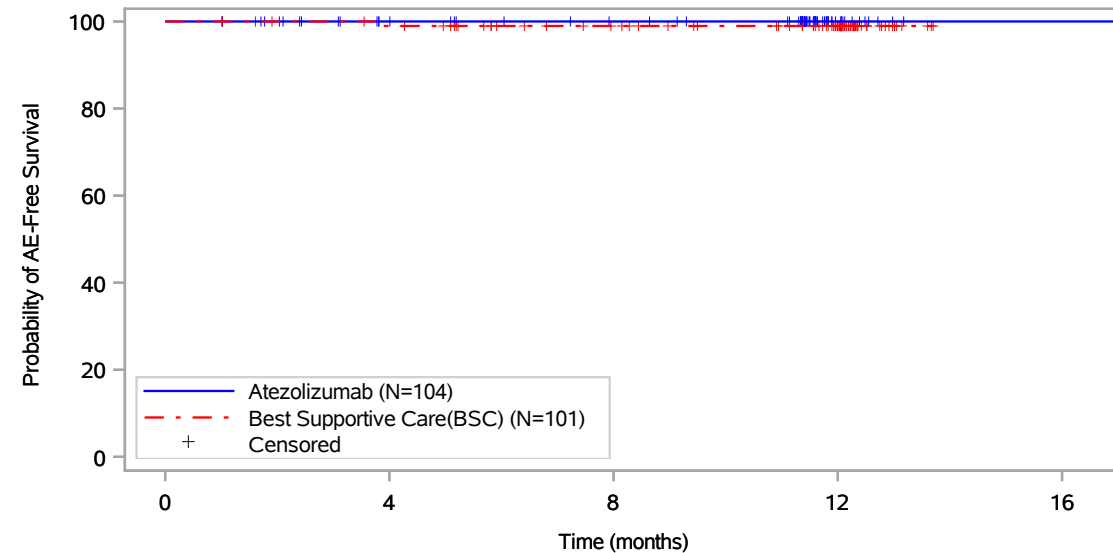
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Catarrh



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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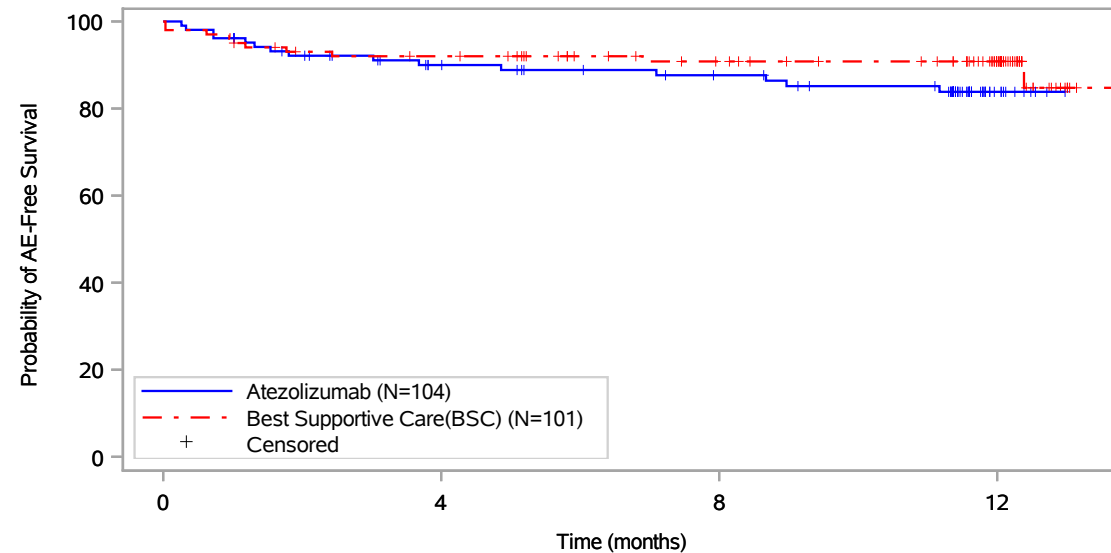
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Cough



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	80	71	10
Best Supportive Care(BSC) (N=101)	101	89	74	49
Patients censored				
Atezolizumab (N=104)	0	14	21	79
Best Supportive Care(BSC) (N=101)	0	4	18	43

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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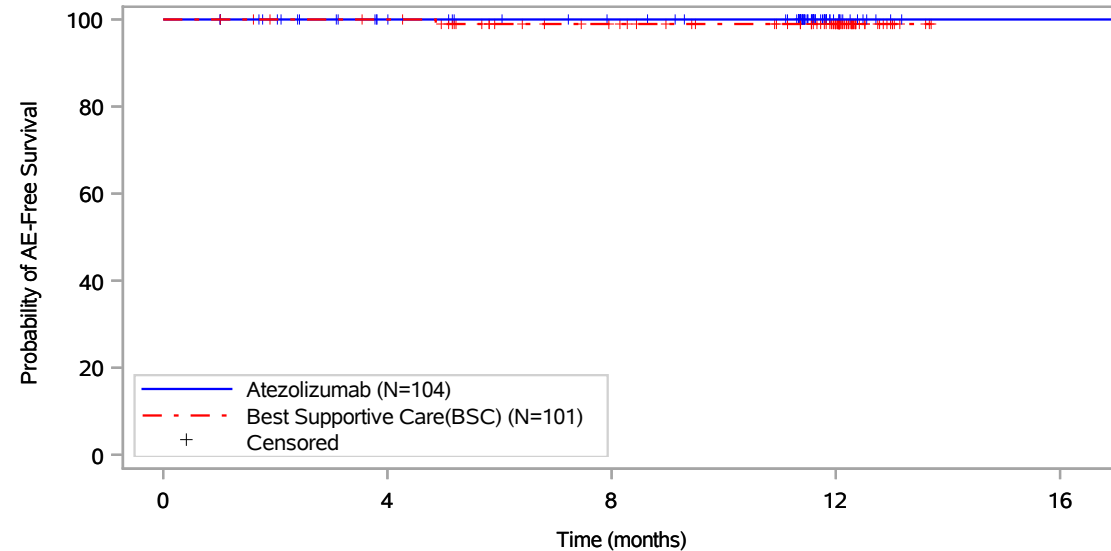
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dysphonia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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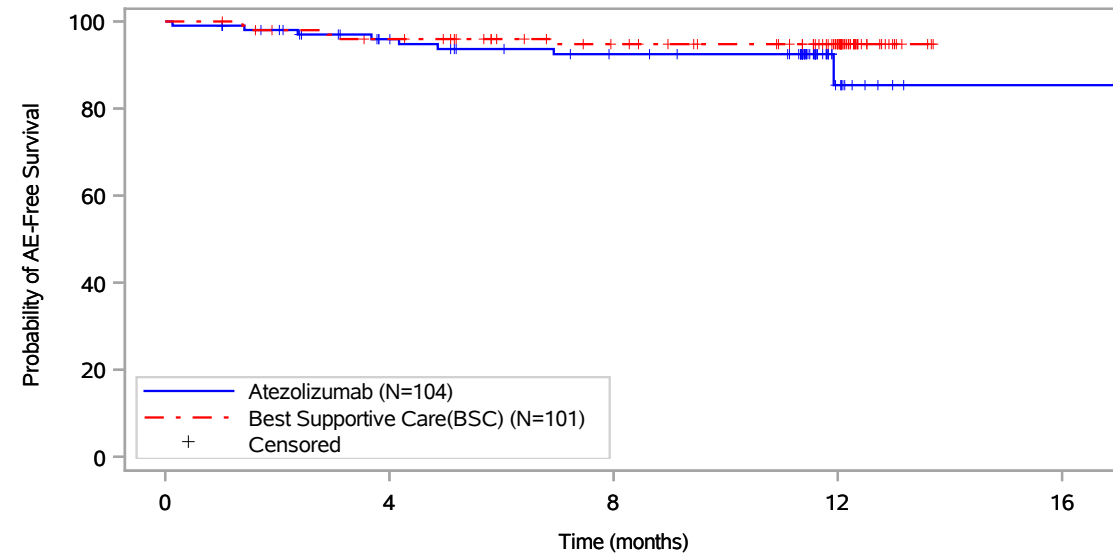
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	76	11	1
Best Supportive Care(BSC) (N=101)	101	93	79	52	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	85	95
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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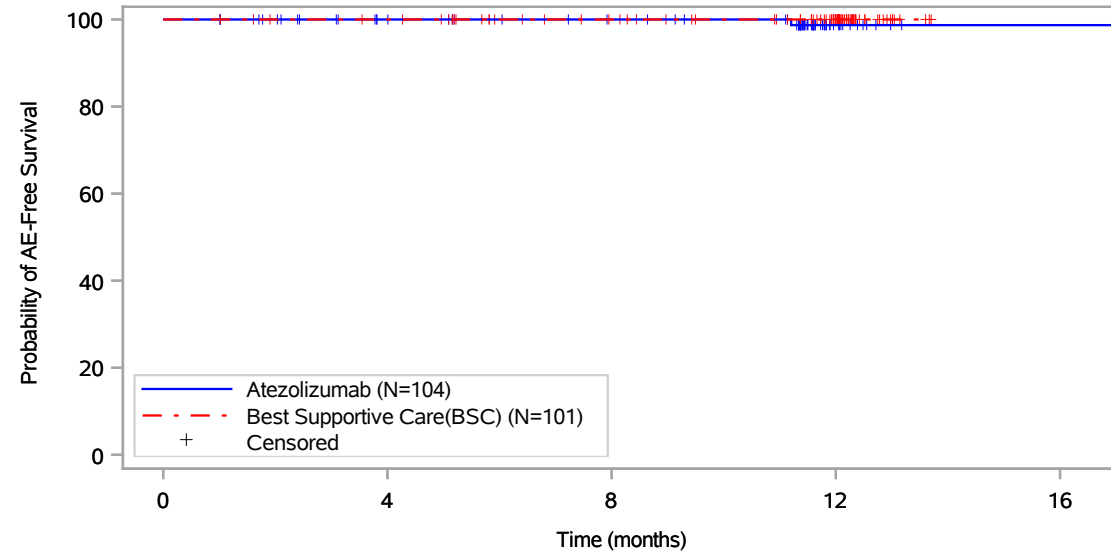
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Haemoptysis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care (BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care (BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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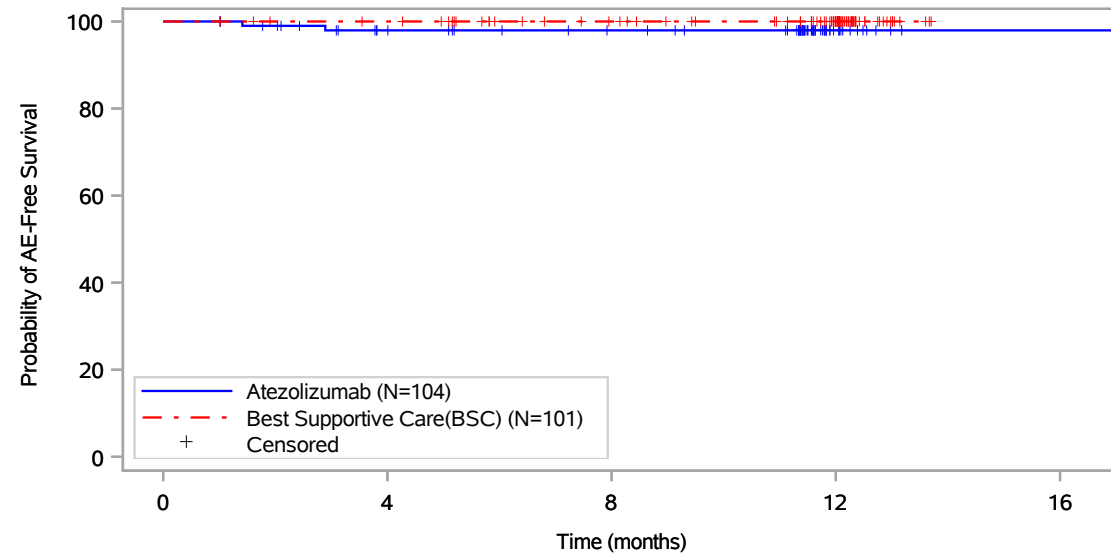
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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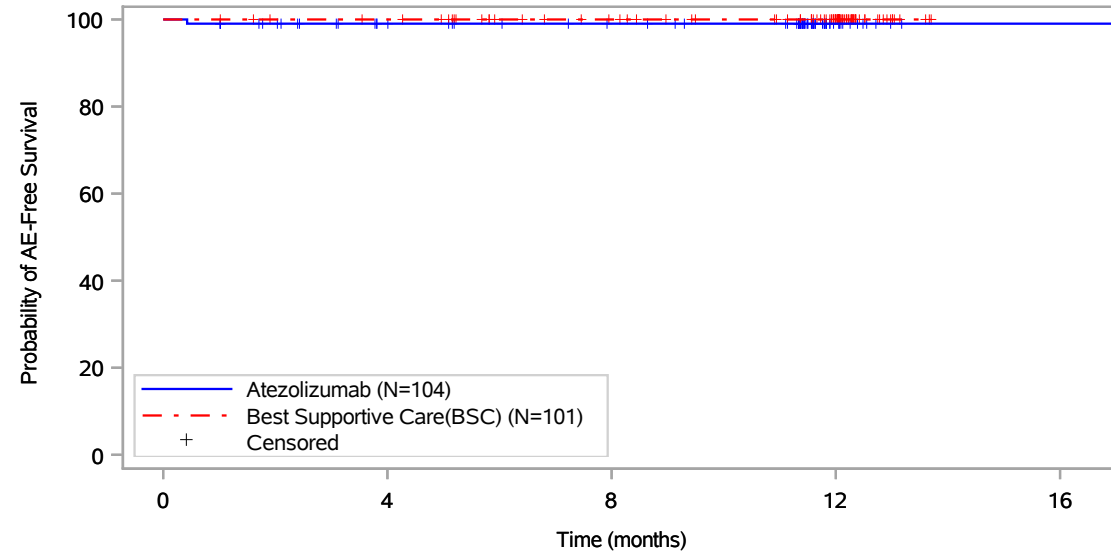
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Laryngospasm



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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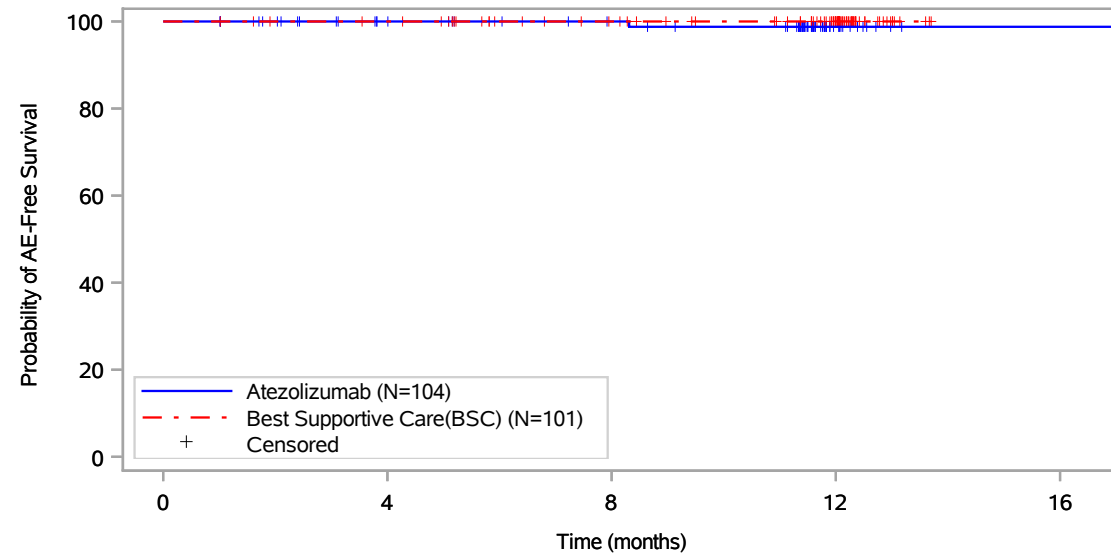
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Lung disorder



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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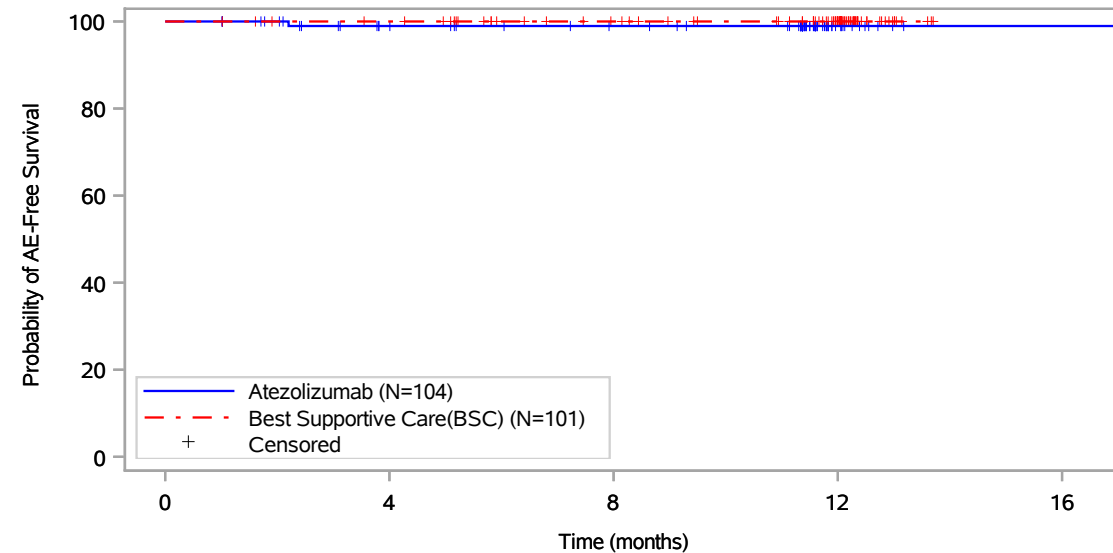
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Nasal congestion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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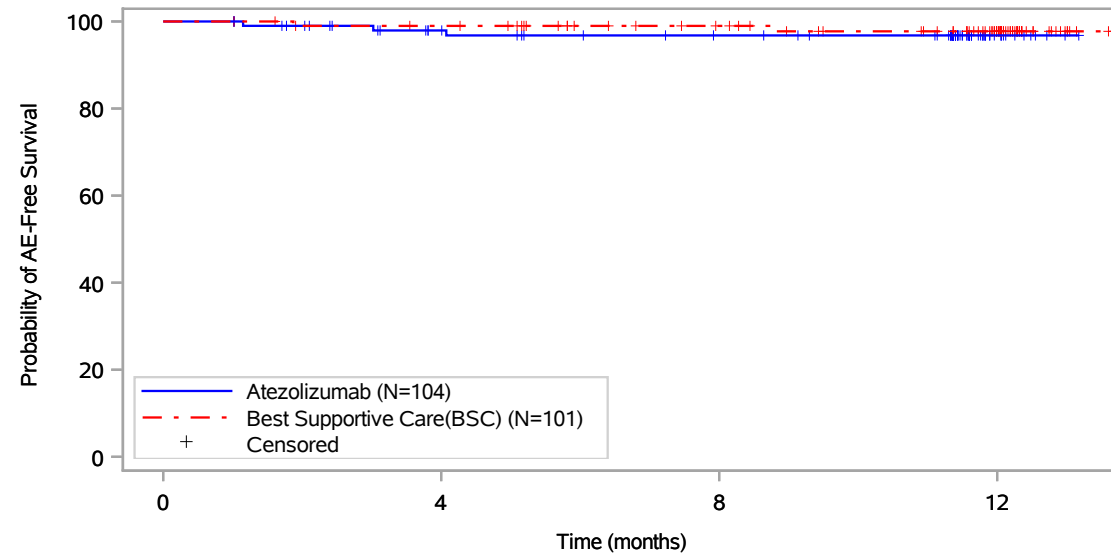
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Oropharyngeal pain



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	87	79	12
Best Supportive Care(BSC) (N=101)	101	96	82	53
Patients censored				
Atezolizumab (N=104)	0	15	22	89
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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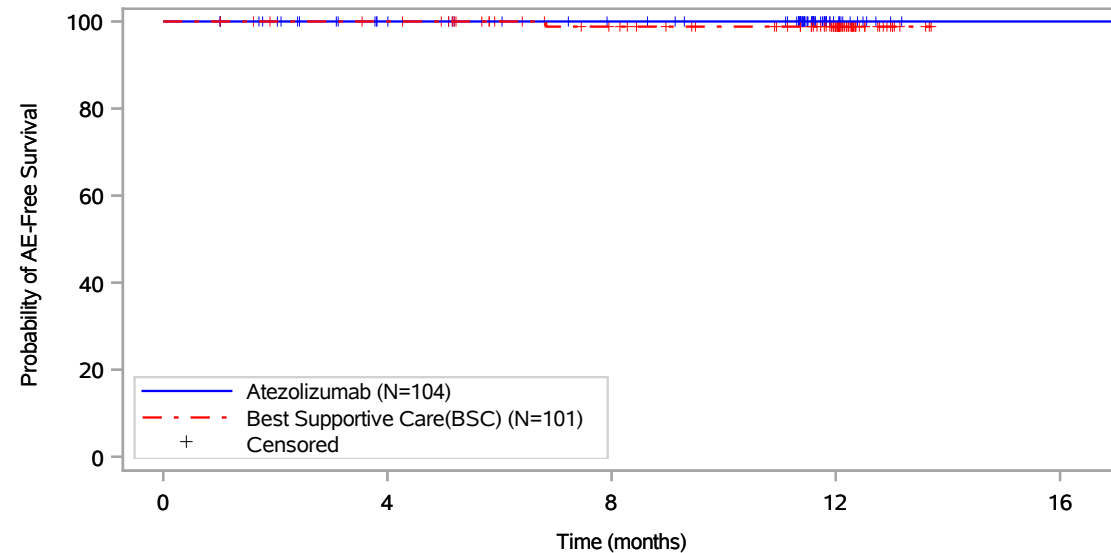
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pleurisy



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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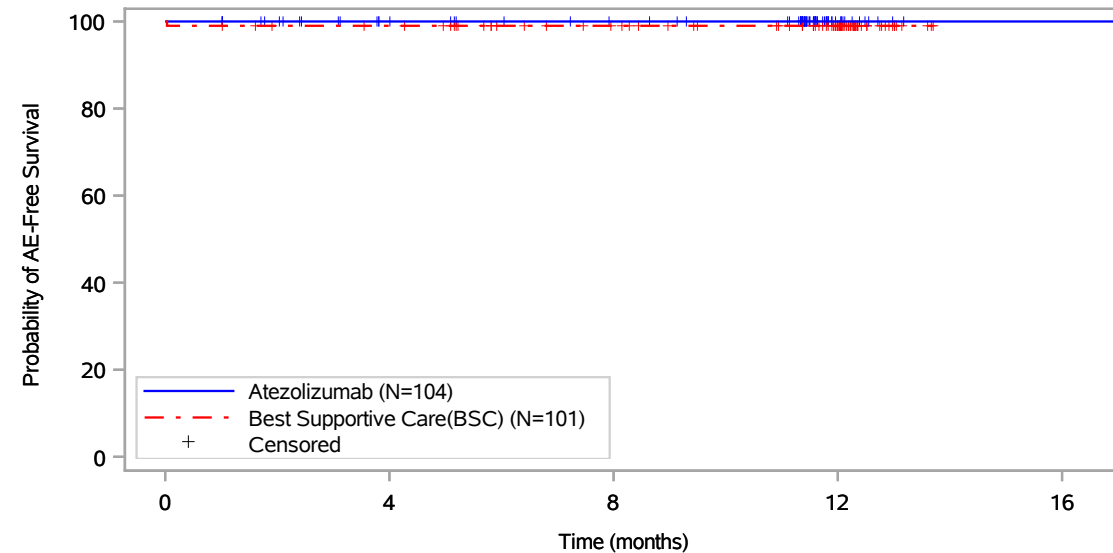
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pleuritic pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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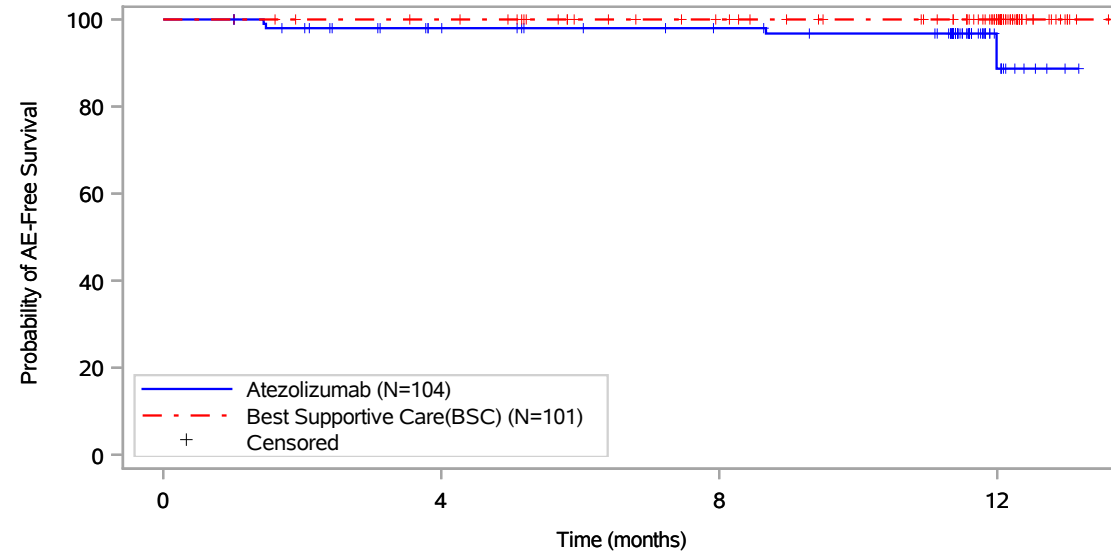
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pneumonitis



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	88	81	11
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	14	21	89
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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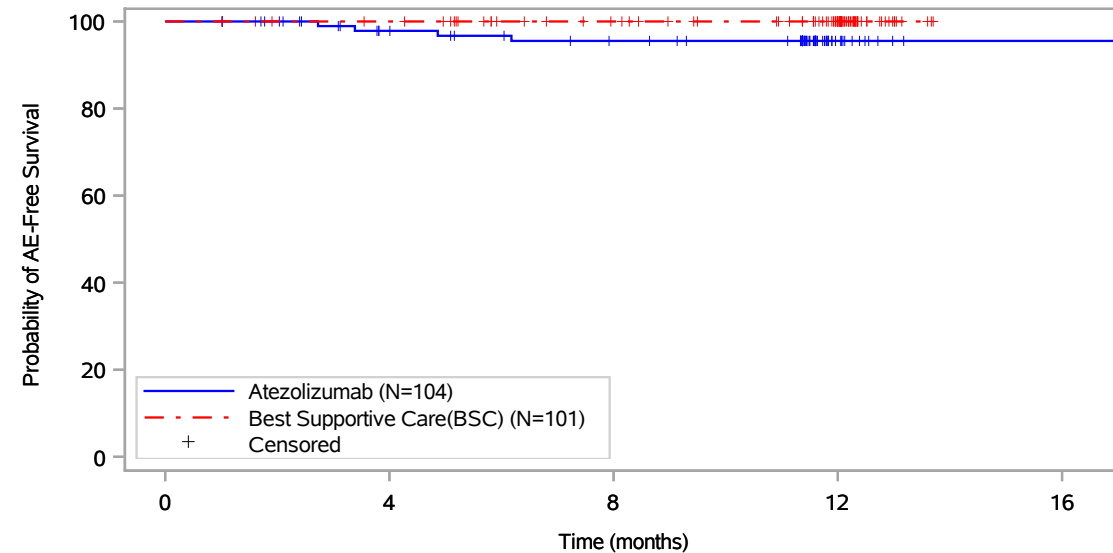
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Productive cough



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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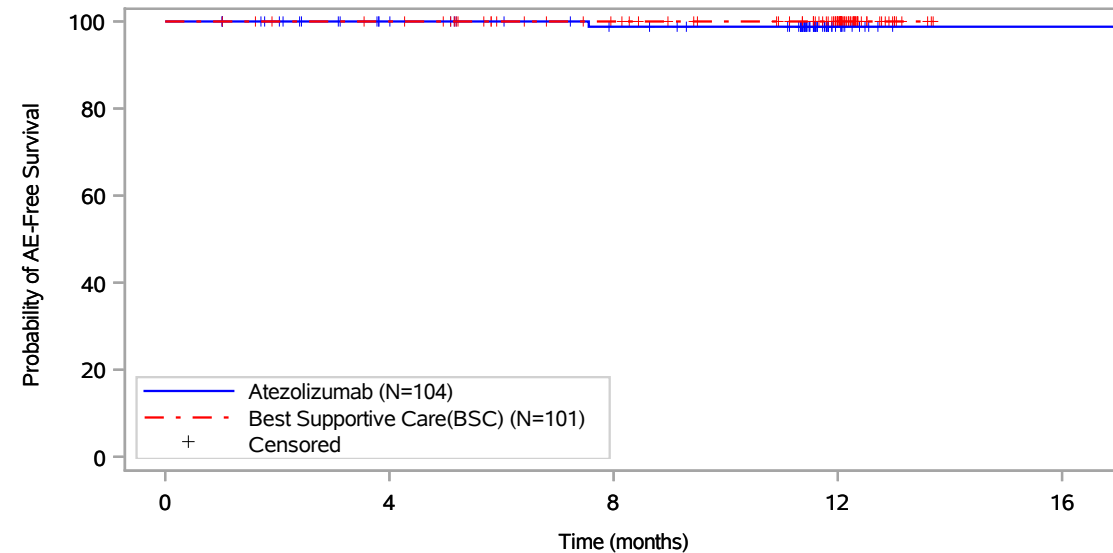
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rates



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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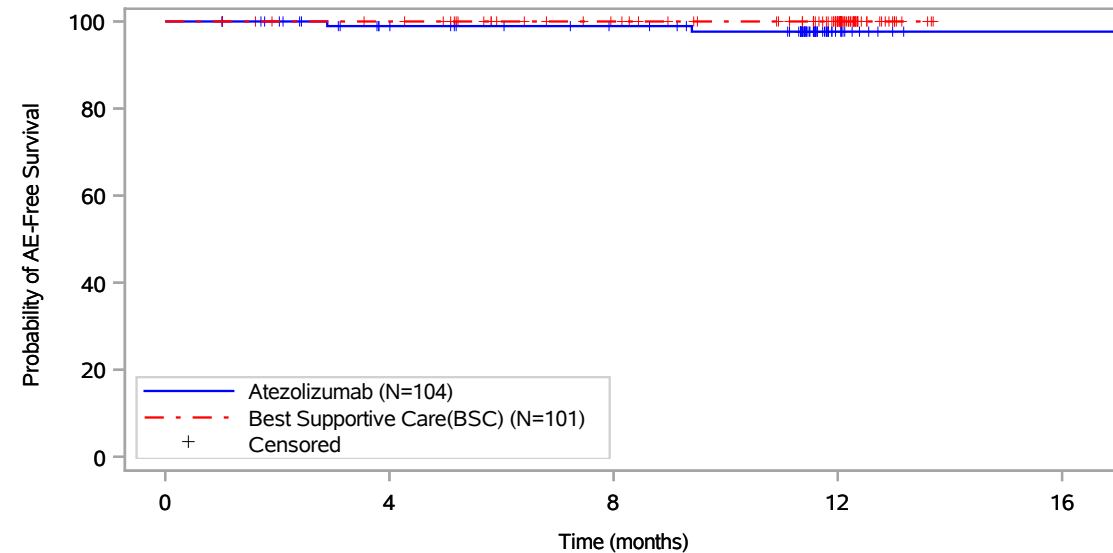
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rhinitis allergic



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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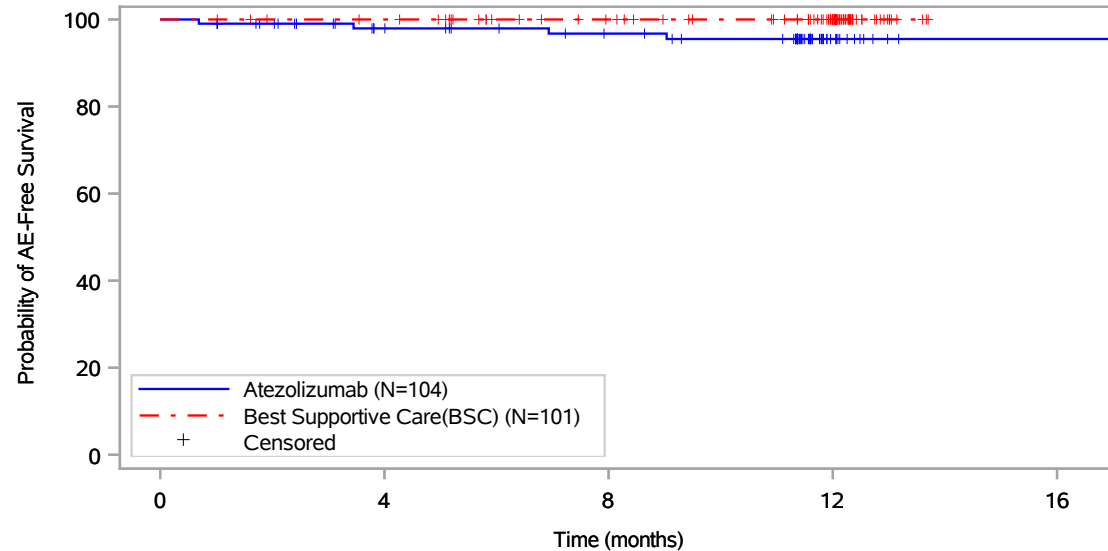
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rhinorrhoea



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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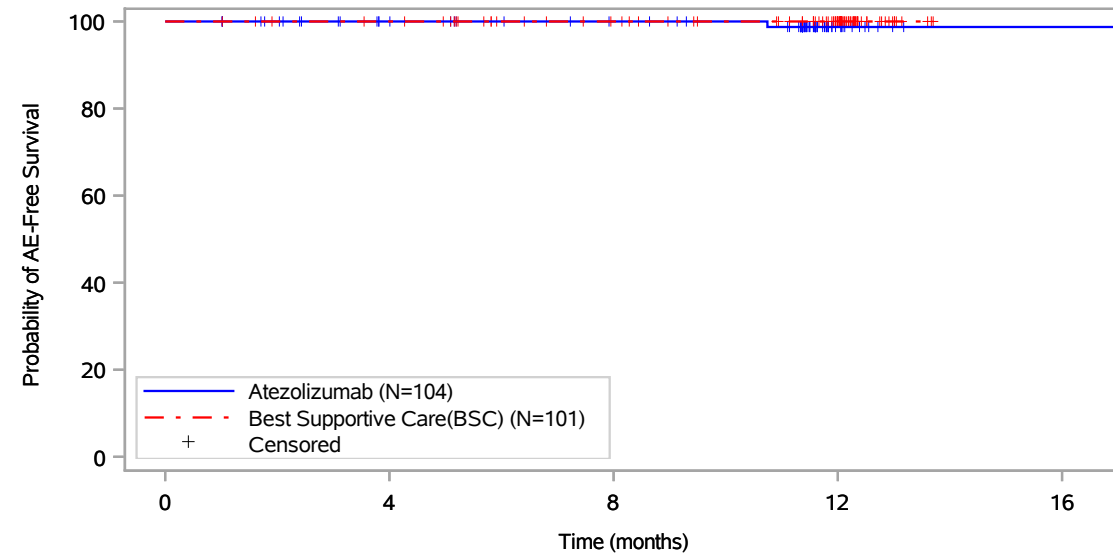
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Sleep apnoea syndrome



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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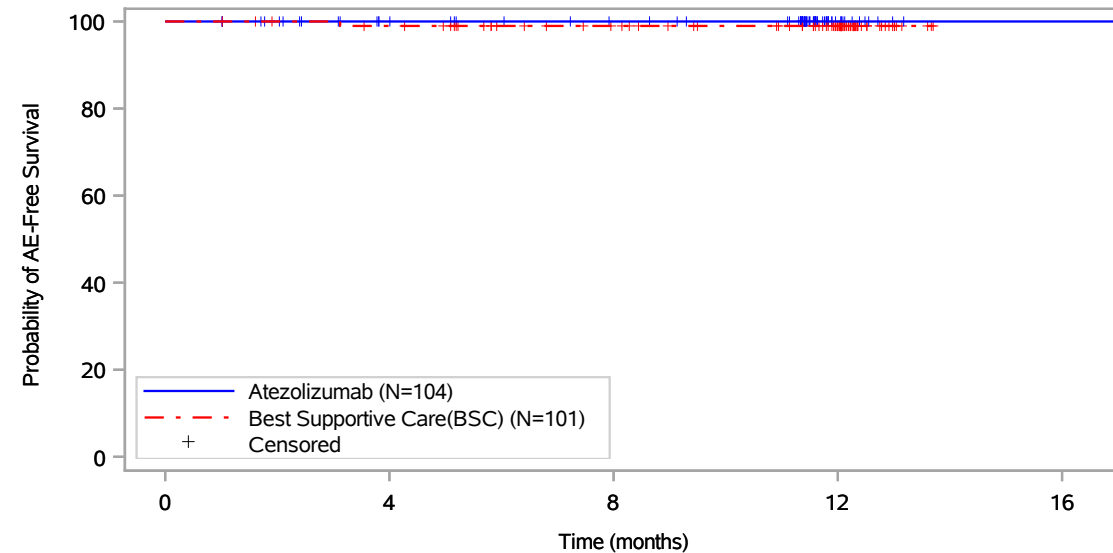
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Upper-airway cough syndrome



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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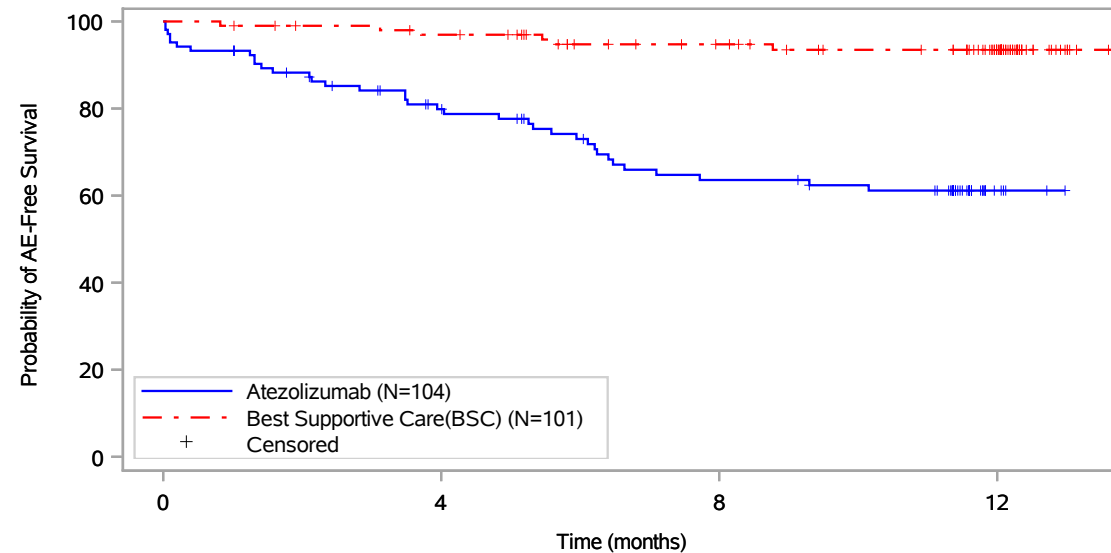
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	73	54	5
Best Supportive Care(BSC) (N=101)	101	94	78	51
Patients censored				
Atezolizumab (N=104)	0	11	16	63
Best Supportive Care(BSC) (N=101)	0	4	18	44

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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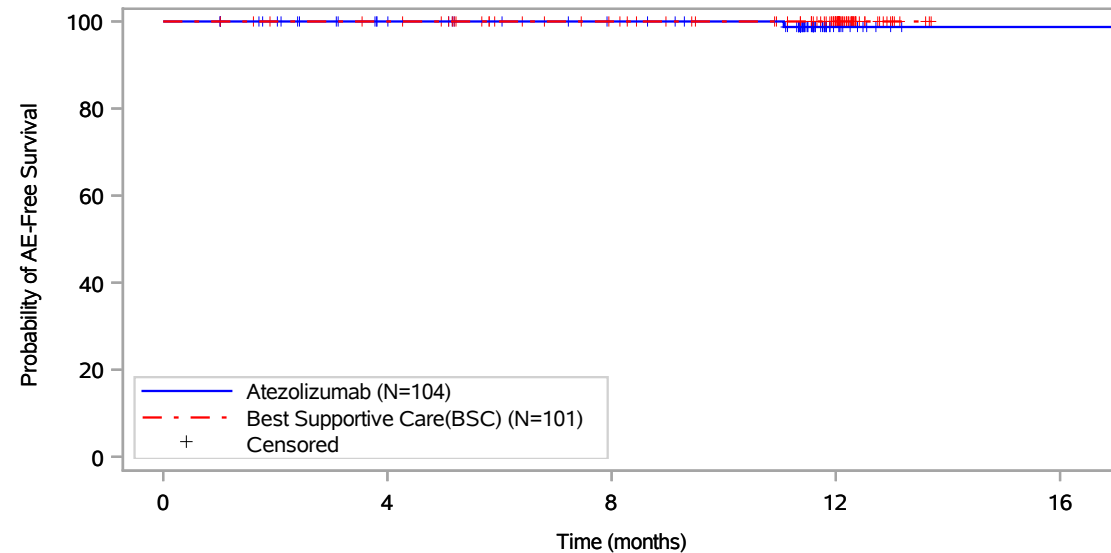
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Actinic keratosis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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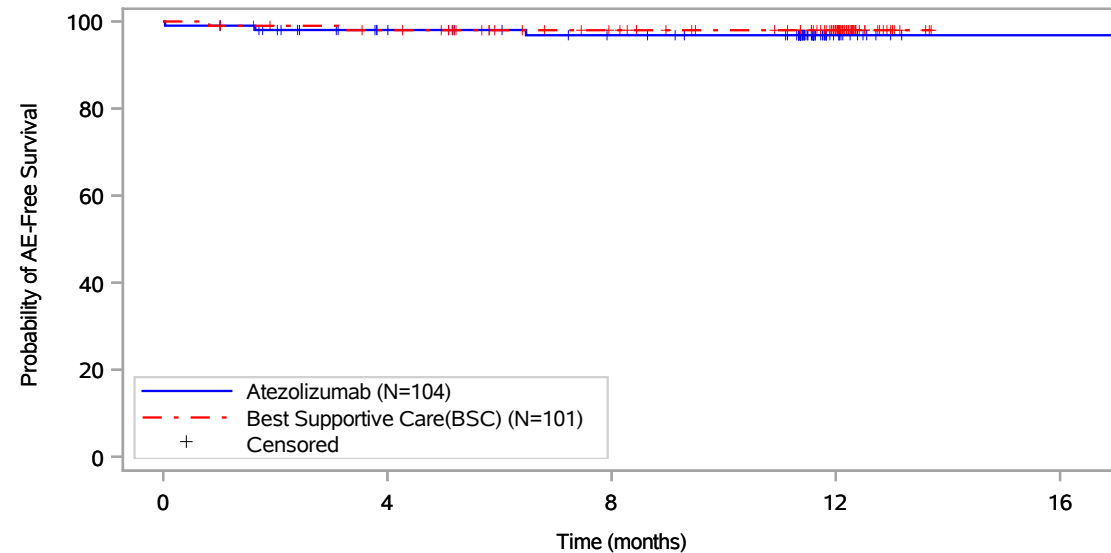
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Alopecia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	87	79	13	1
Best Supportive Care(BSC) (N=101)	101	95	81	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

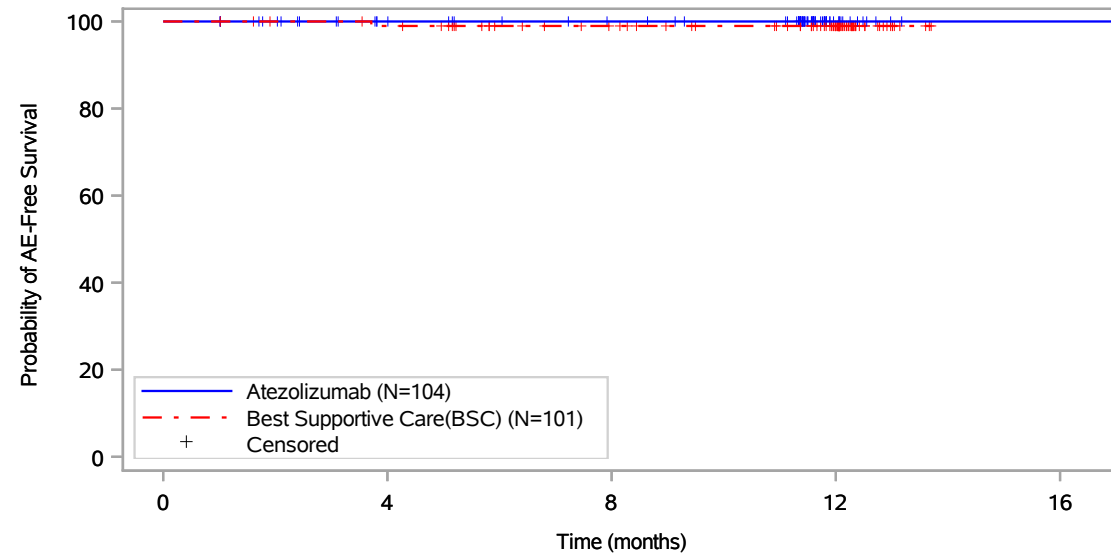
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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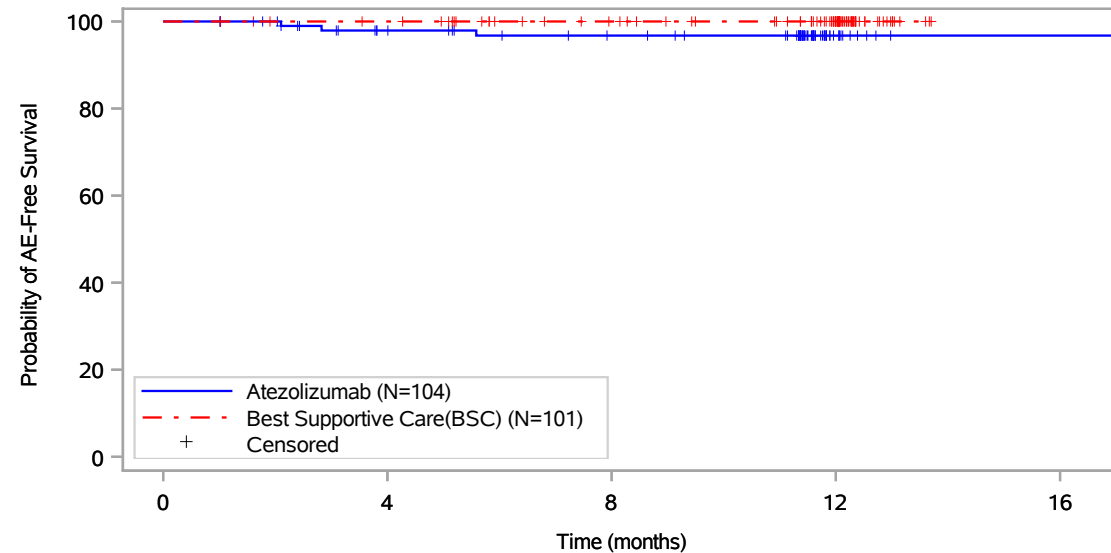
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis acneiform



Patients at risk					
Atezolizumab (N=104)	104	88	80	11	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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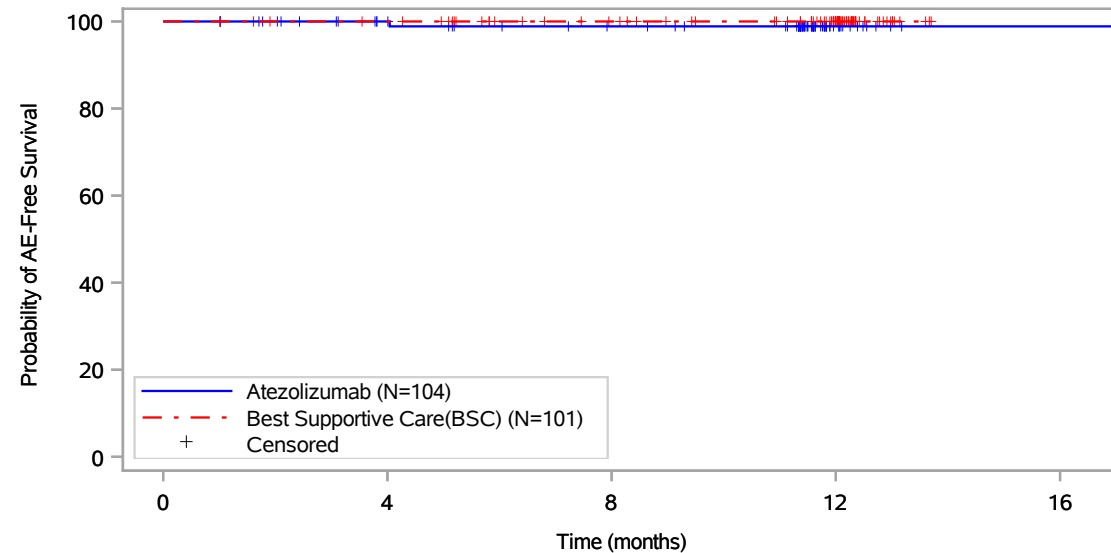
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis exfoliative



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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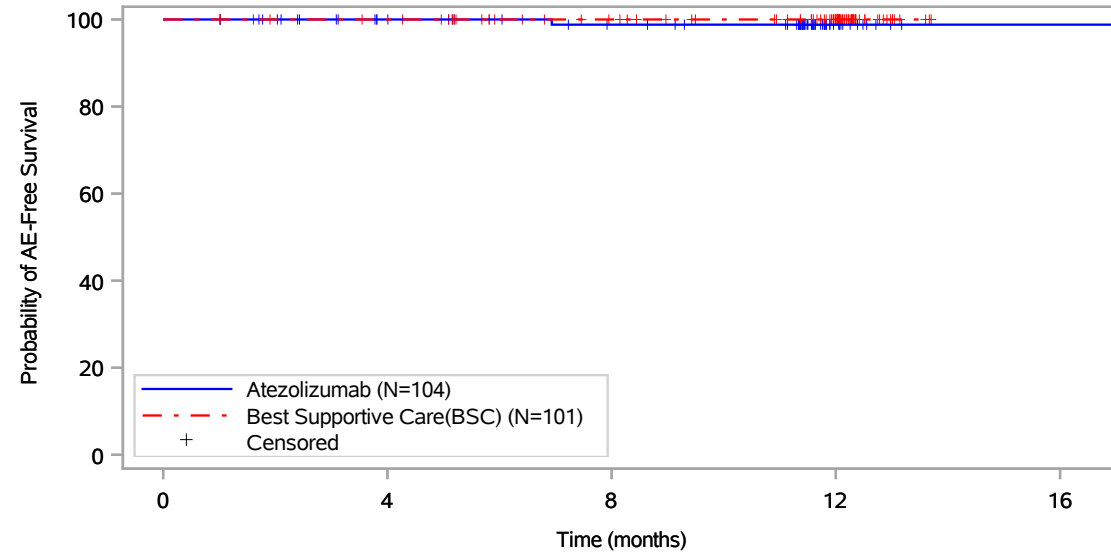
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Drug eruption



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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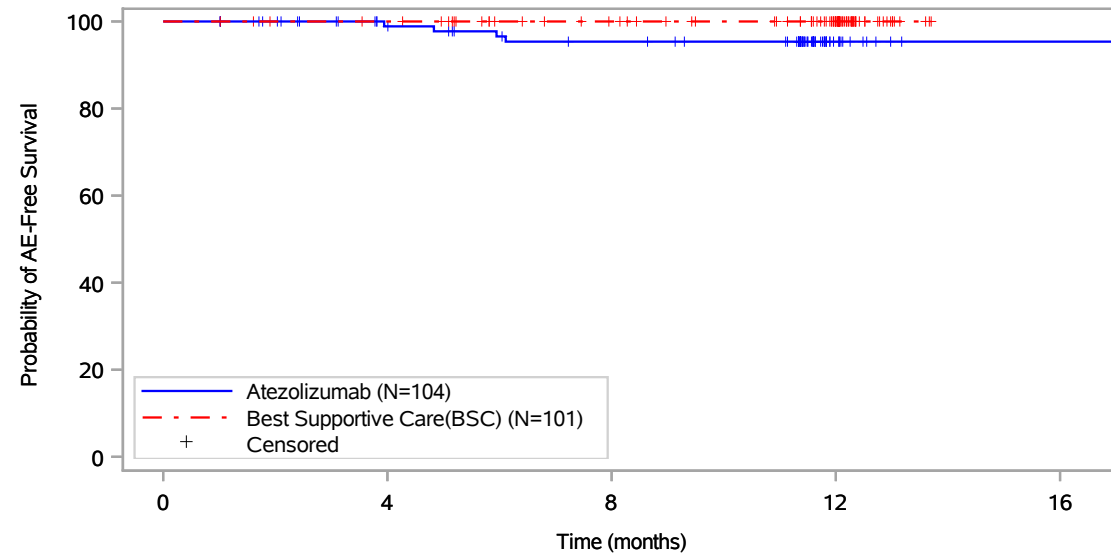
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Dry skin



Patients at risk					
Atezolizumab (N=104)	104	88	79	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	88	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

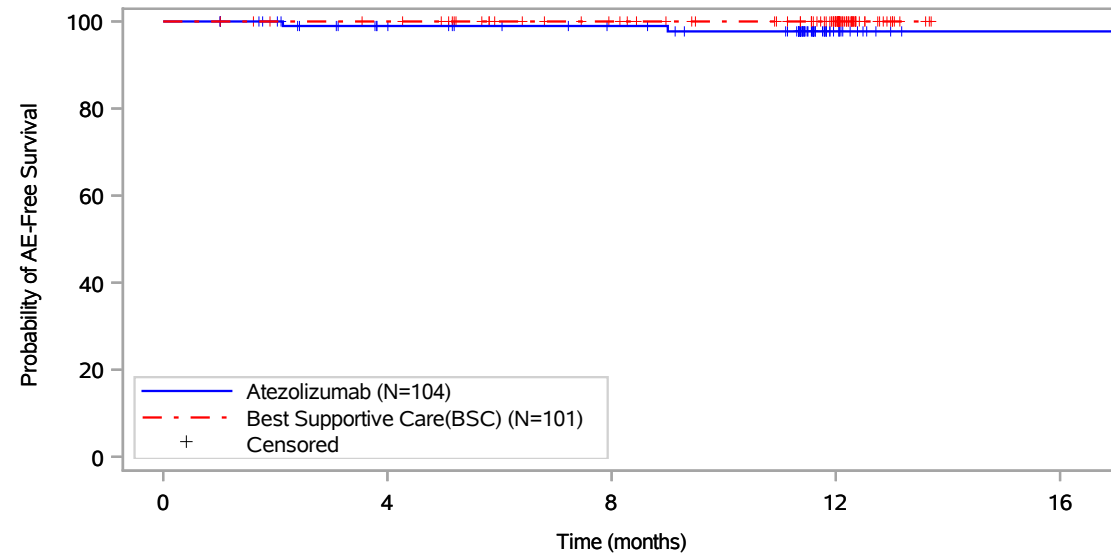
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Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Erythema



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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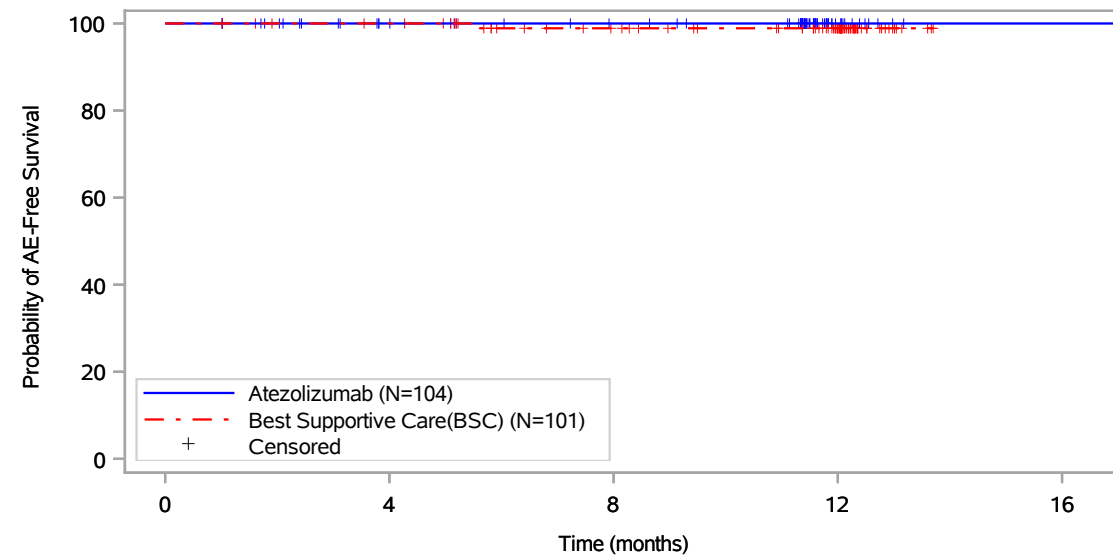
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Miliaria



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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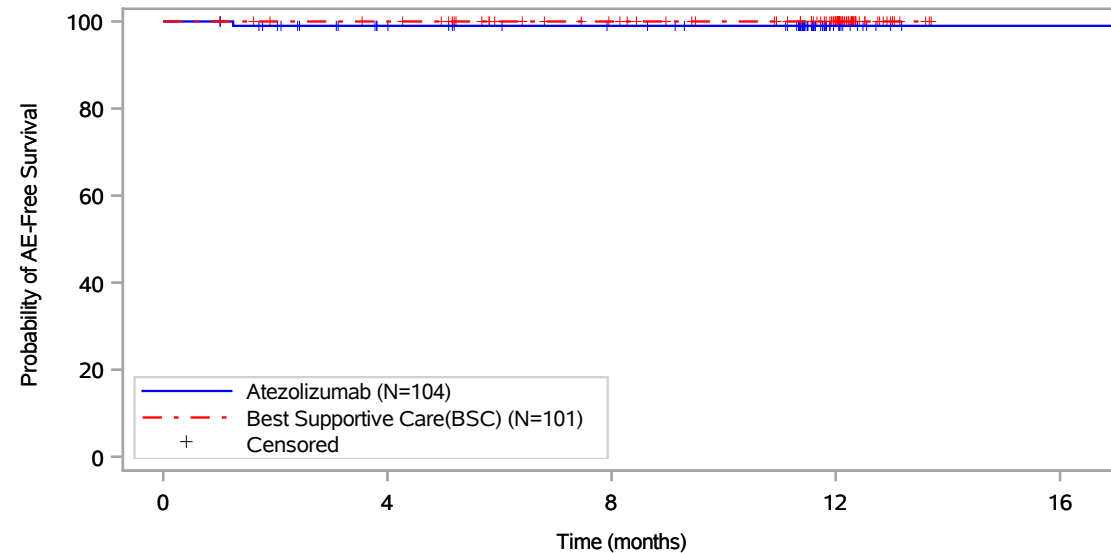
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Onychoclasia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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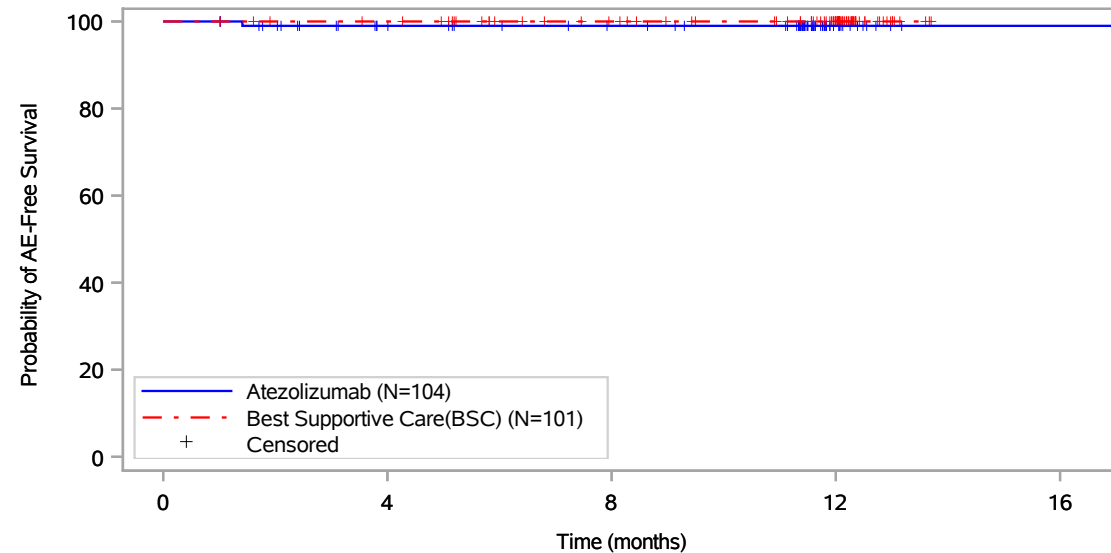
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Papule



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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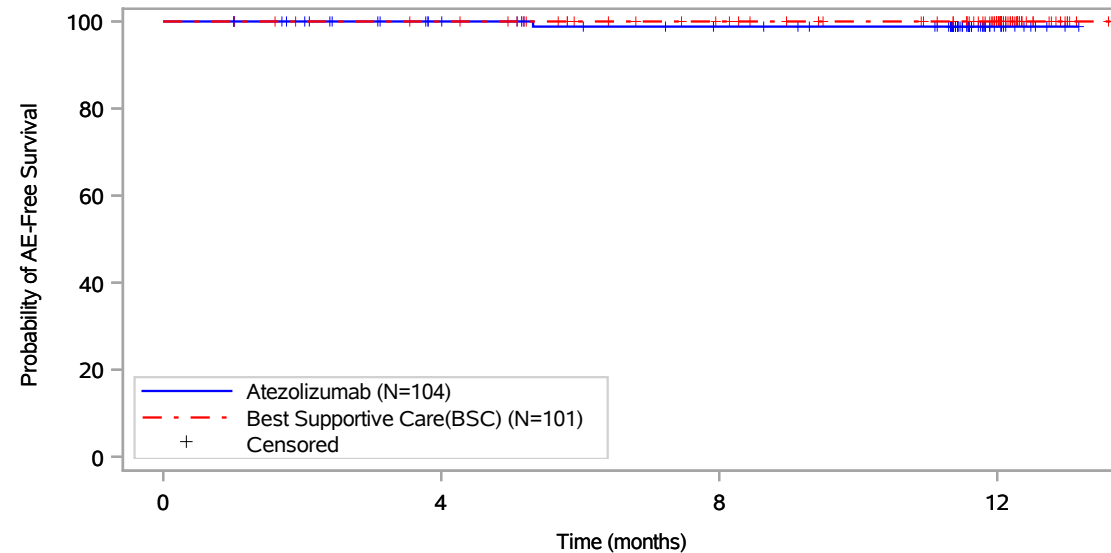
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	89	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	15	22	91
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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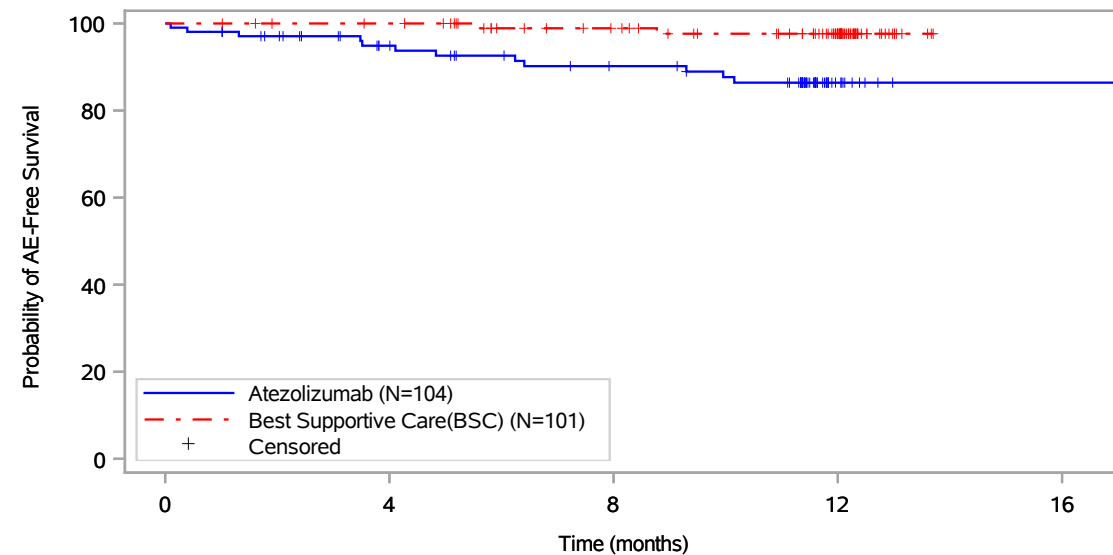
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Pruritus



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	84	73	10	1
Best Supportive Care(BSC) (N=101)	101	97	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	82	91
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

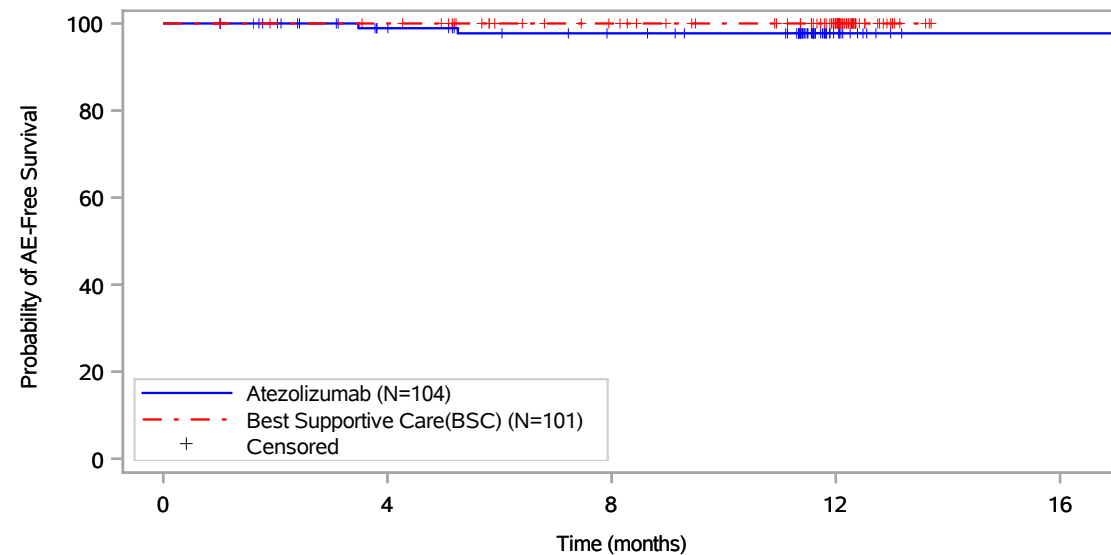
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Psoriasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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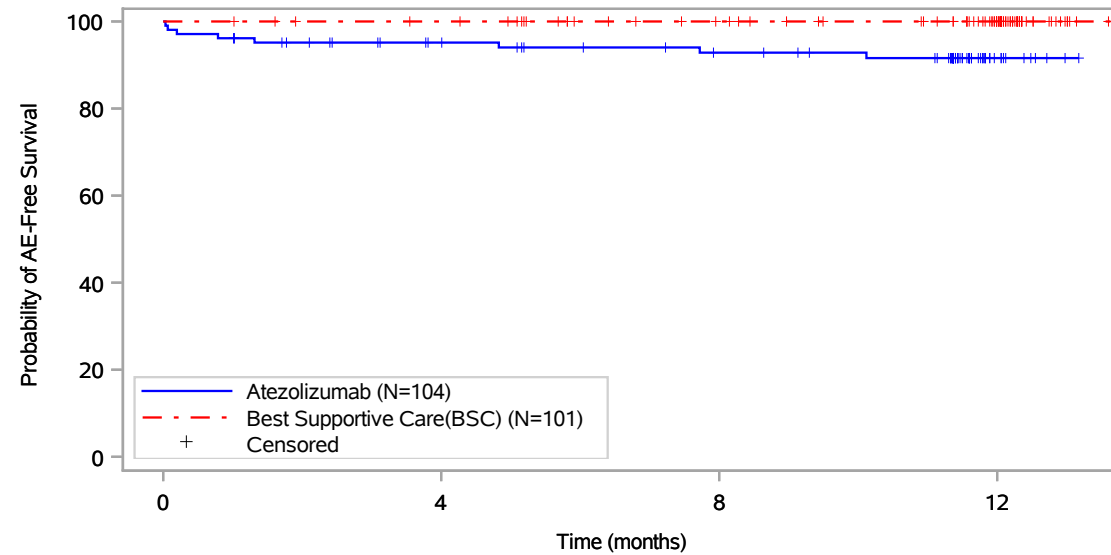
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



Patients at risk				
Atezolizumab (N=104)	104	86	77	10
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	13	20	86
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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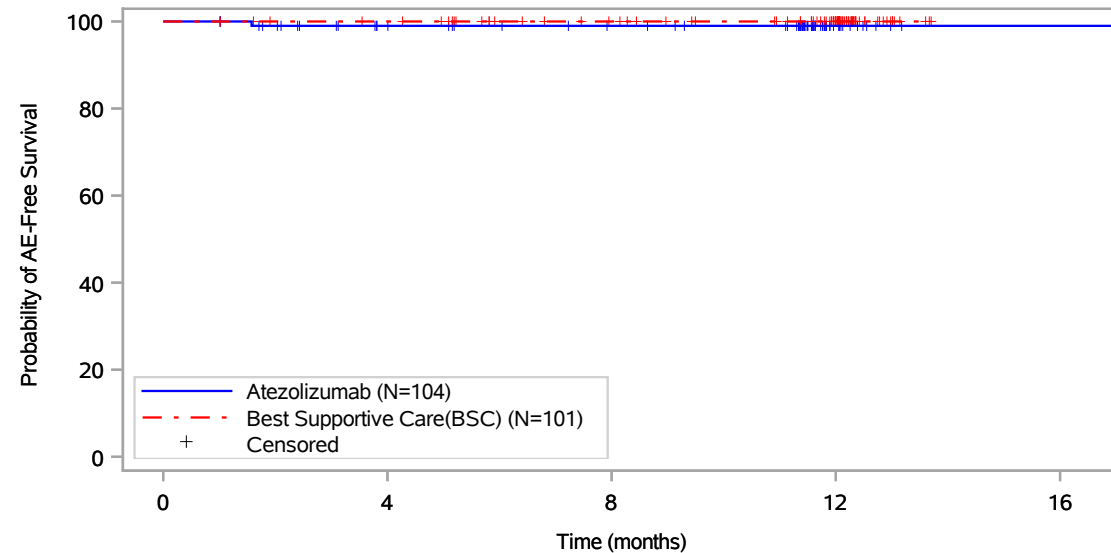
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash erythematous



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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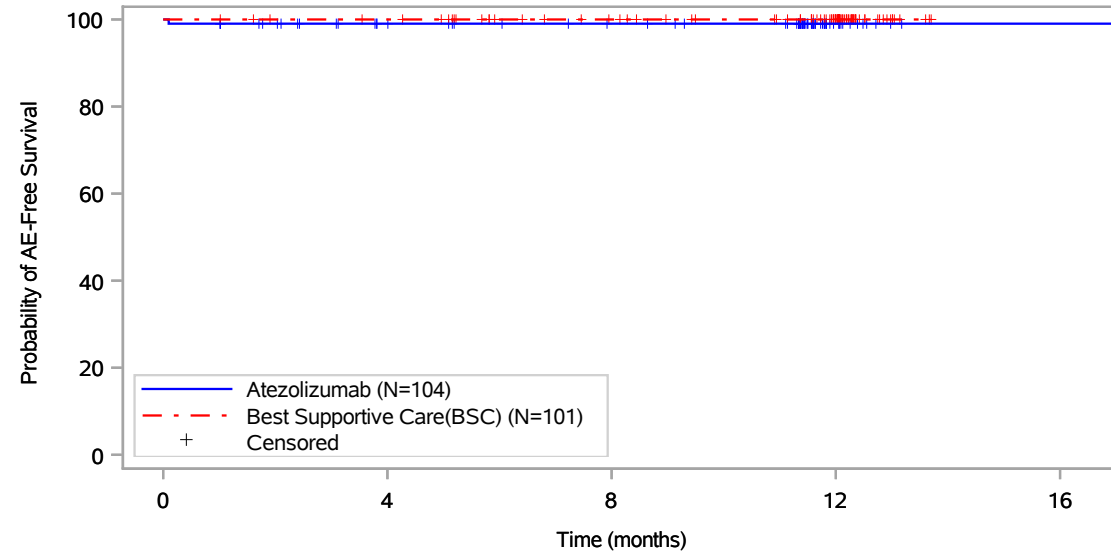
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash maculo-papular



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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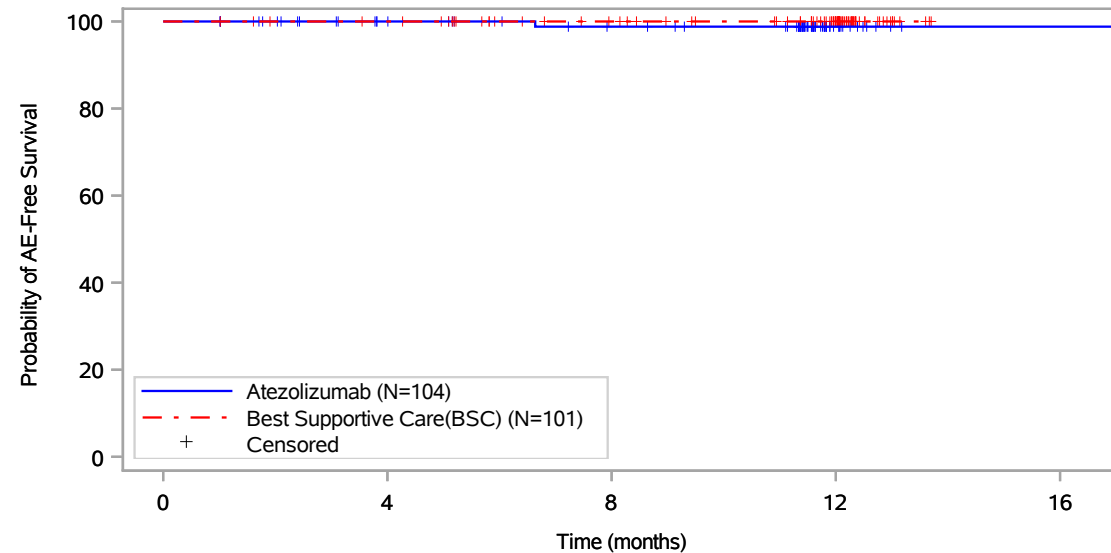
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash pruritic



Patients at risk					
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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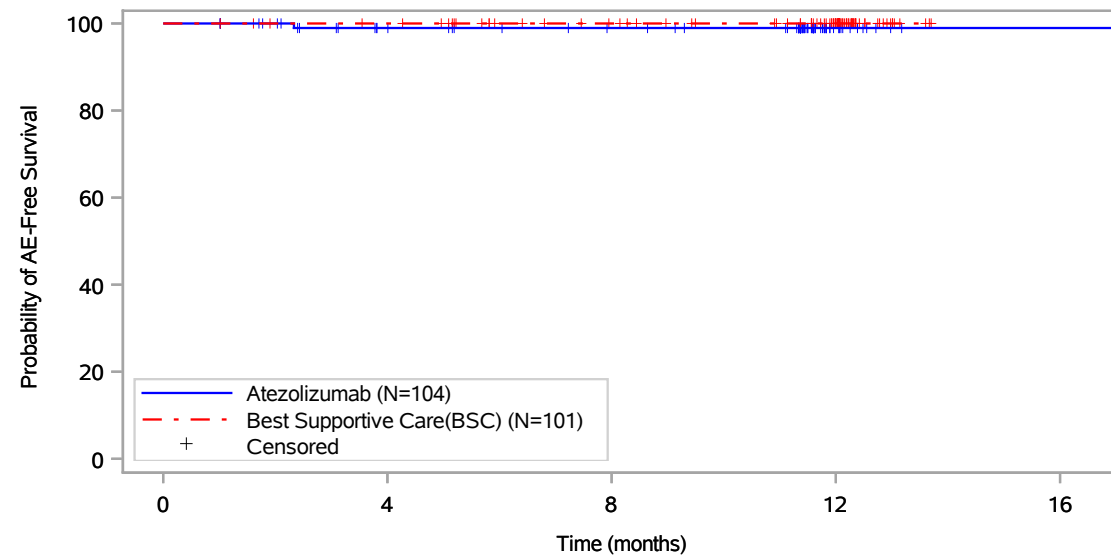
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Scar pain



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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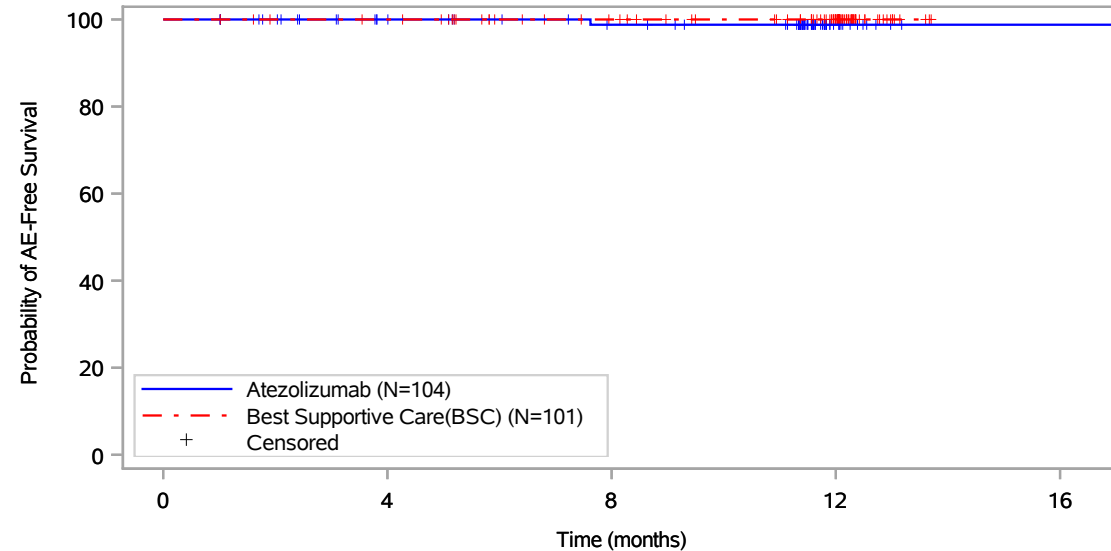
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Skin burning sensation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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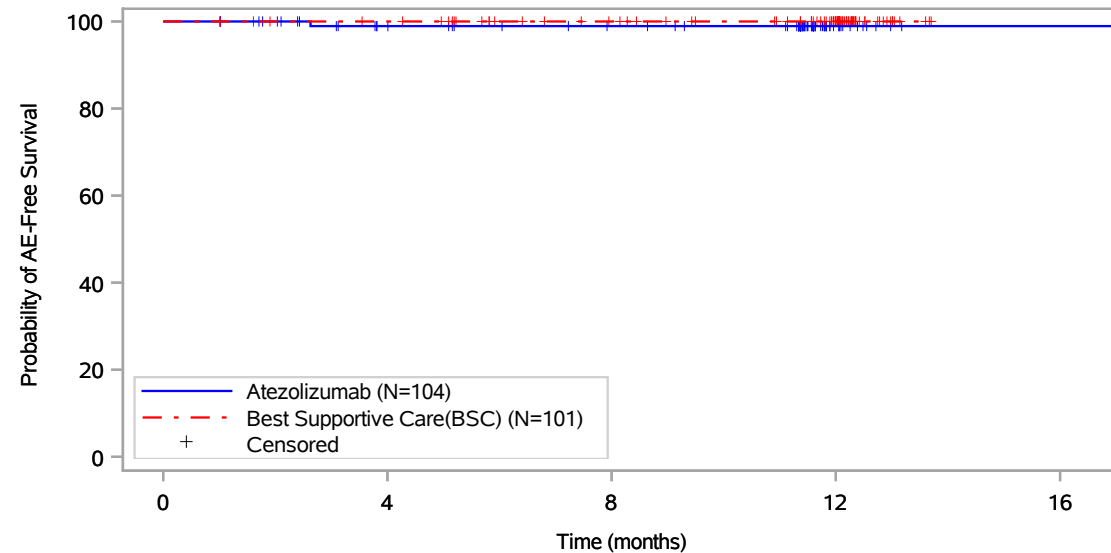
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Skin exfoliation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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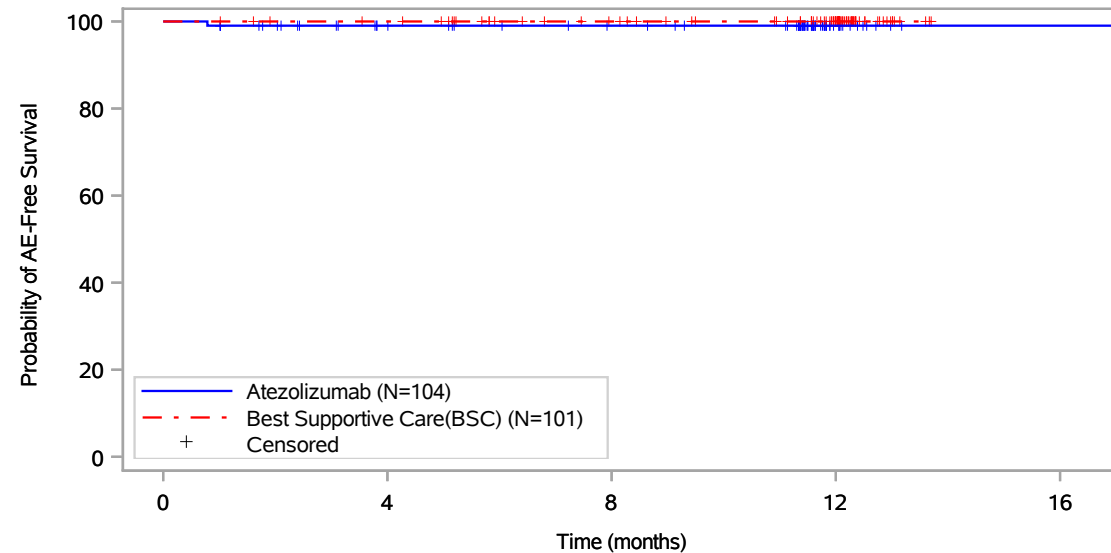
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Toxic skin eruption



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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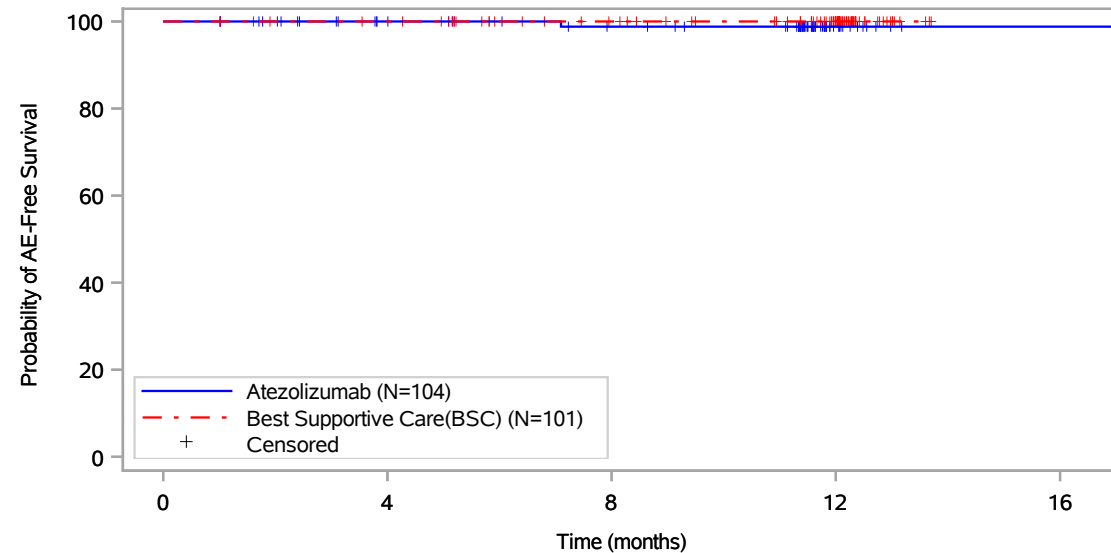
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Urticaria



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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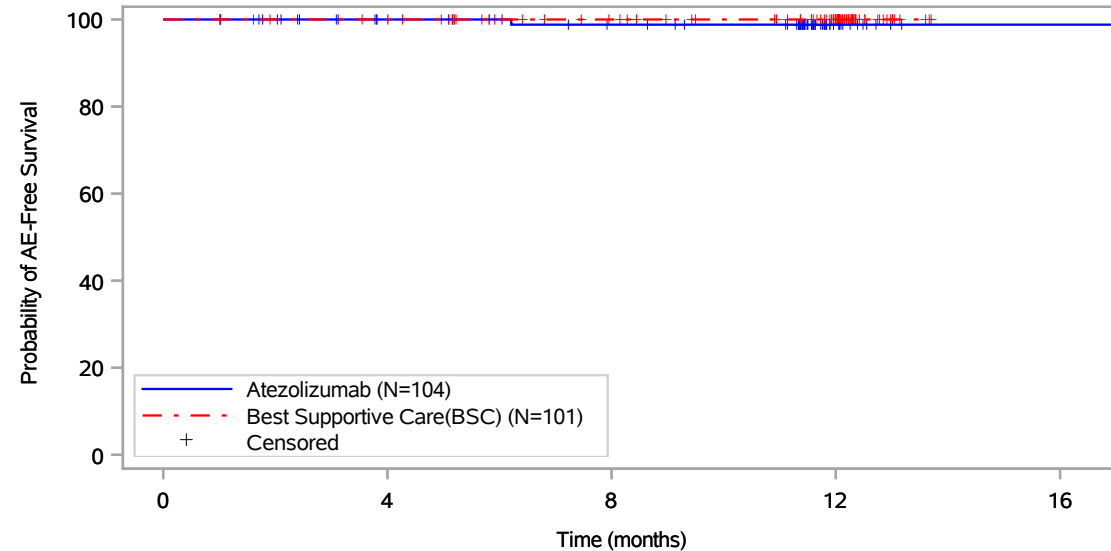
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Vitiligo



Patients at risk					
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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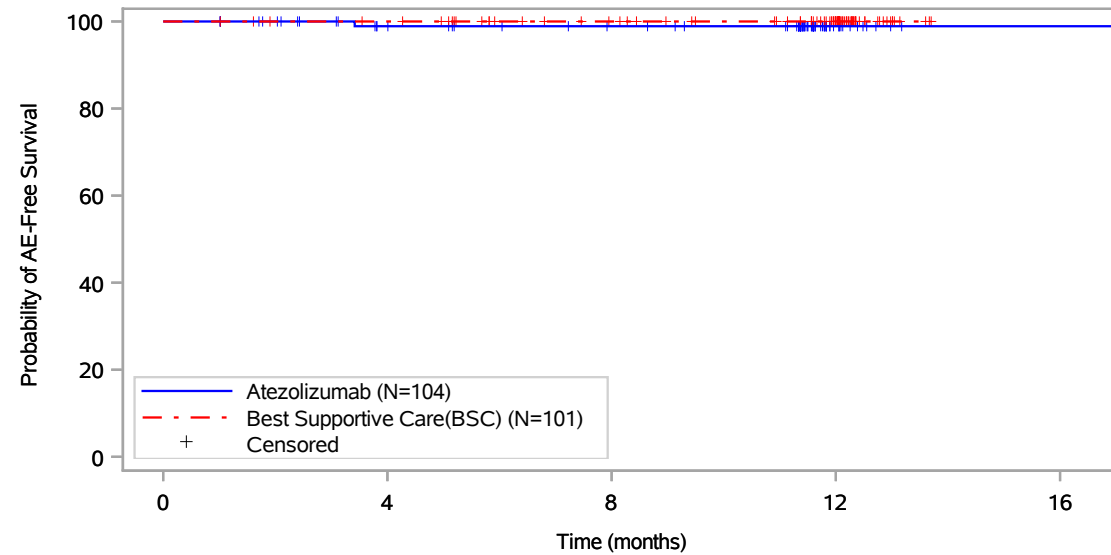
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Surgical and medical procedures, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

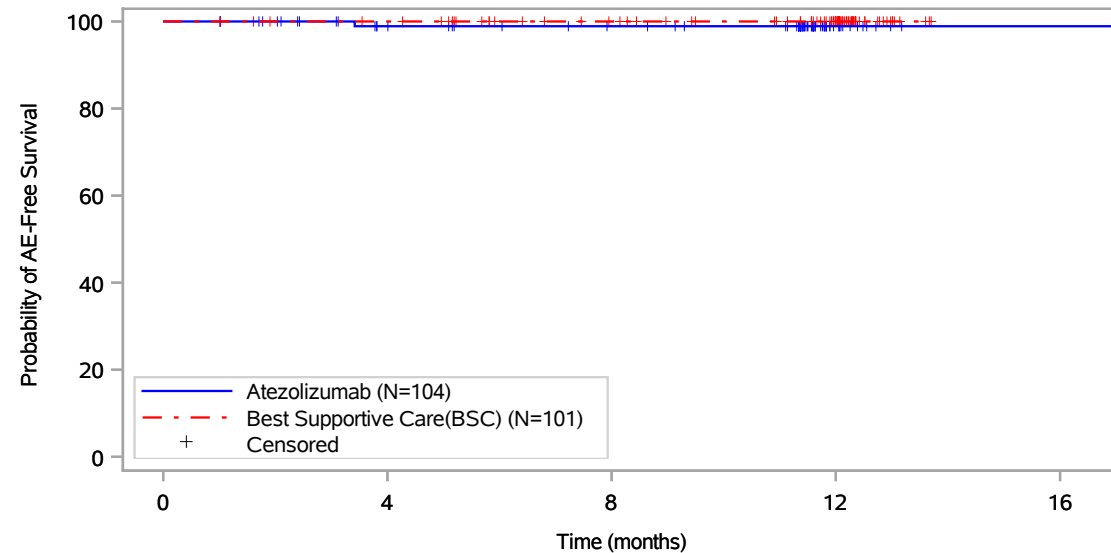
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Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Surgical and medical procedures, Cancer surgery



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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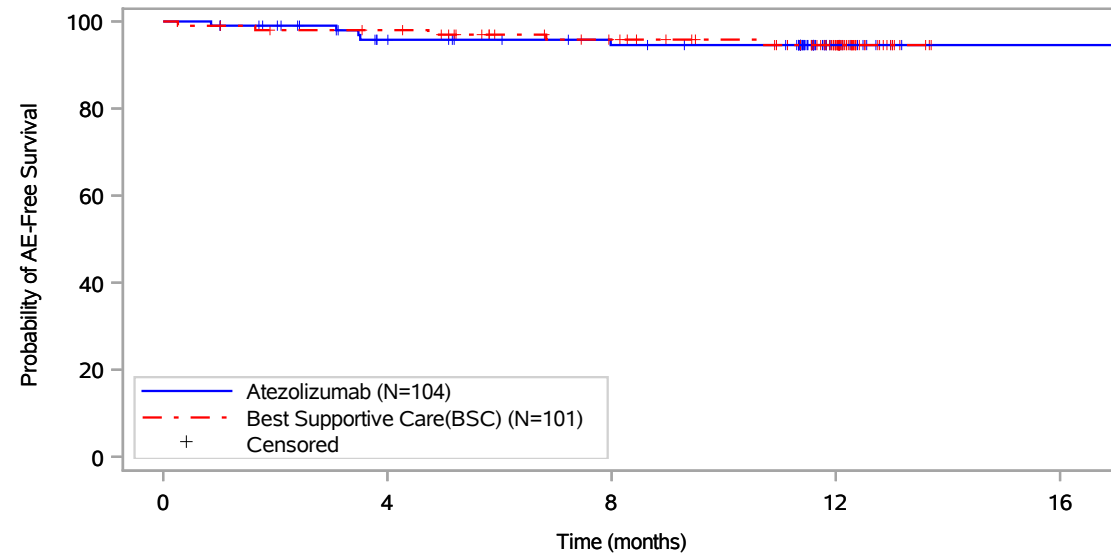
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, All



Patients at risk					
Atezolizumab (N=104)	104	85	78	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	86	98
Best Supportive Care(BSC) (N=101)	0	3	15	43	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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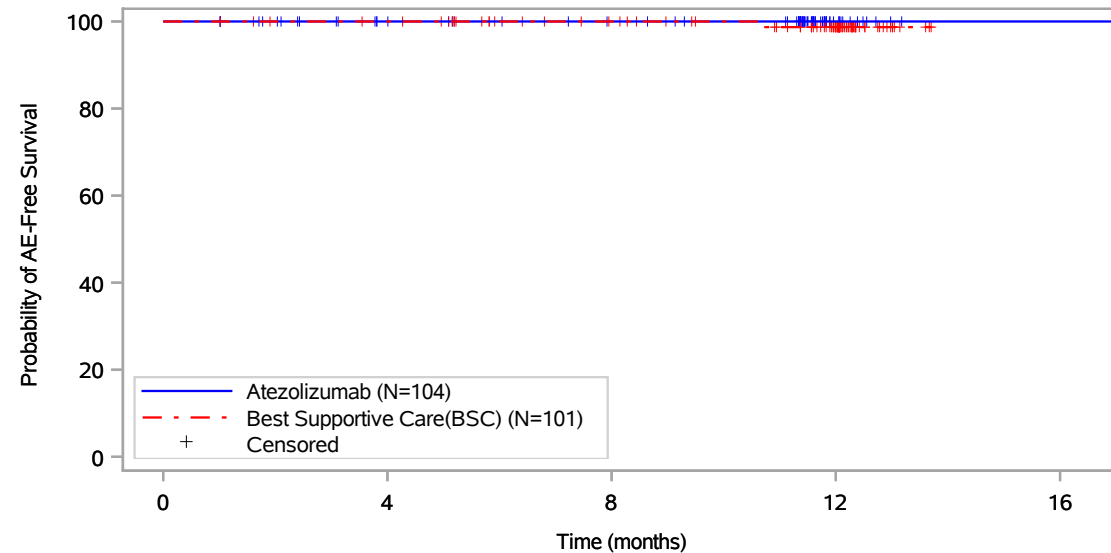
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Hot flush



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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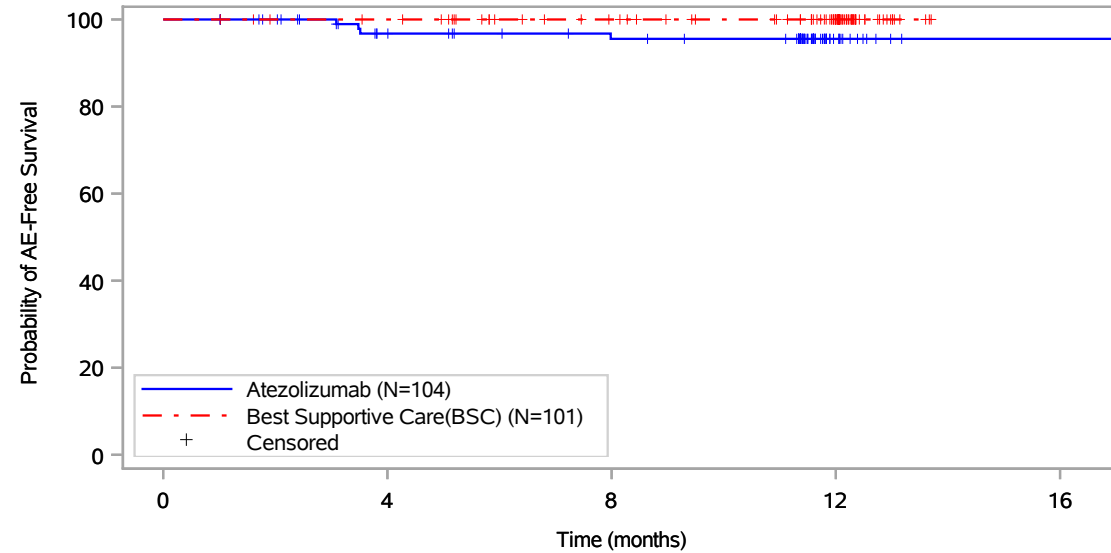
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Hypertension



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	79	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	87	99
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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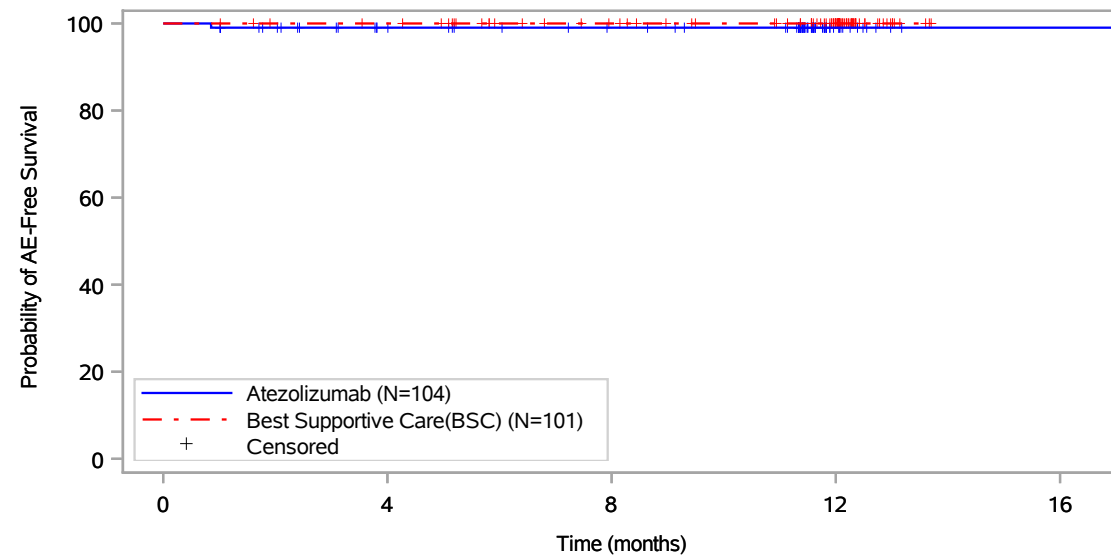
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Hypotension



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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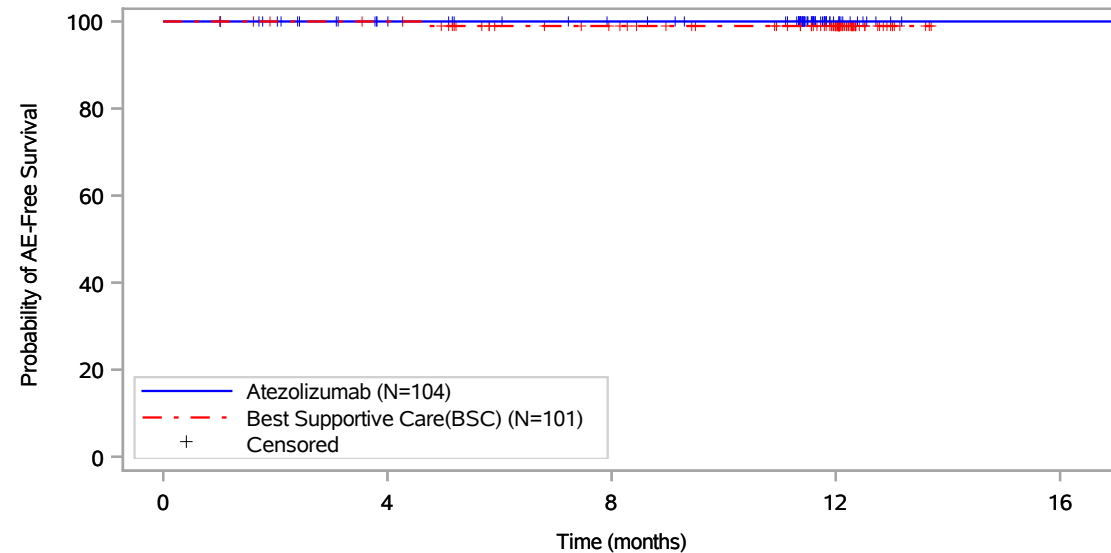
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Orthostatic hypotension



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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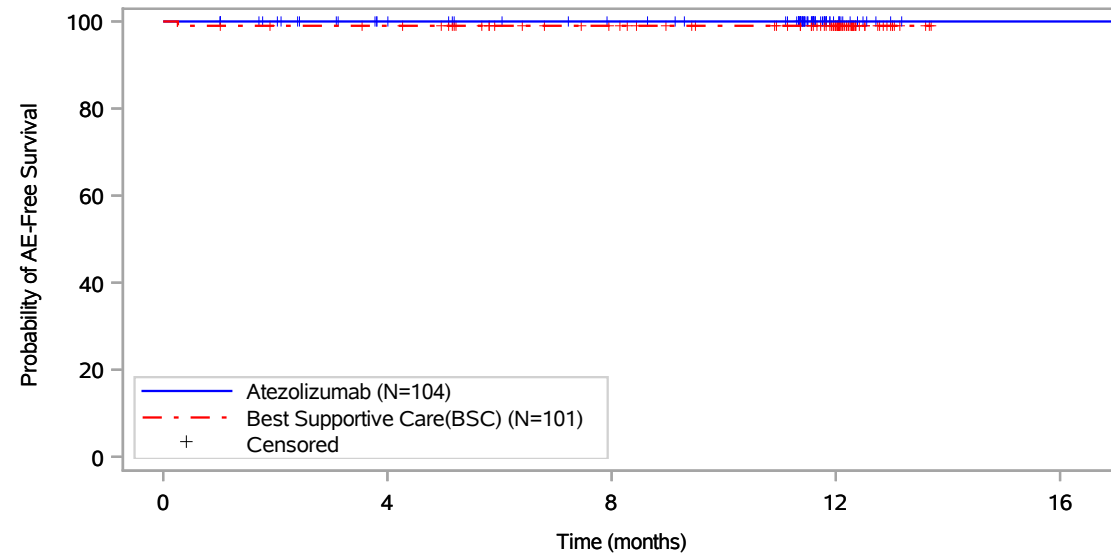
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Phlebitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	3	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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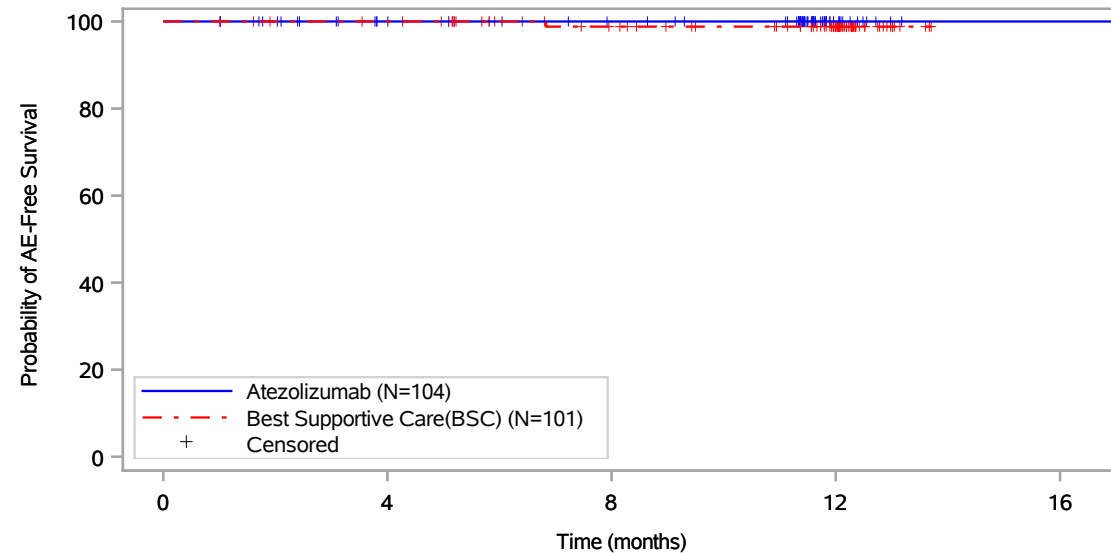
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Phlebitis superficial



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..CE_DFS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
13DEC2021 20:41

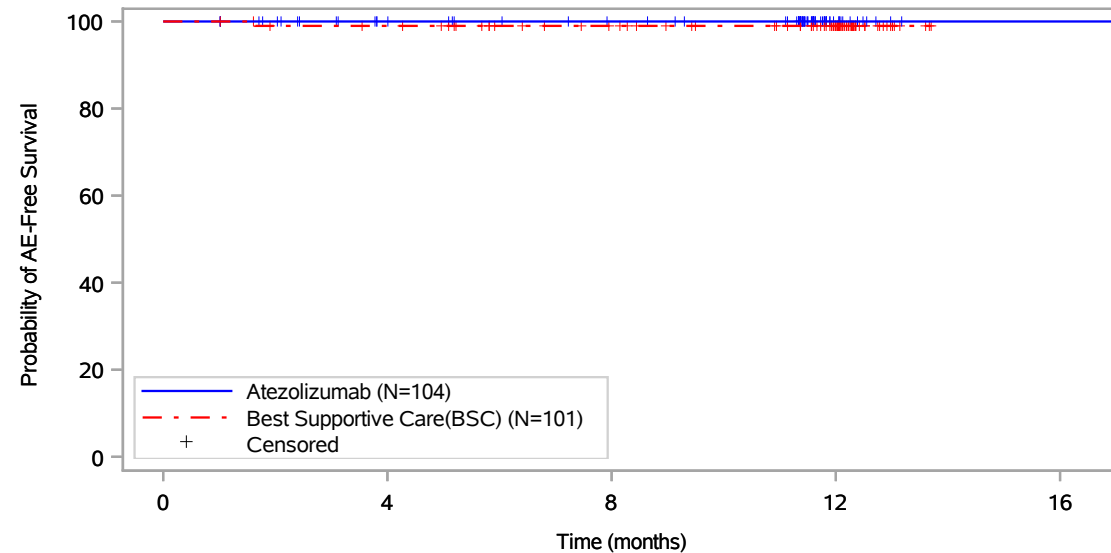
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Vascular disorders, Vascular stenosis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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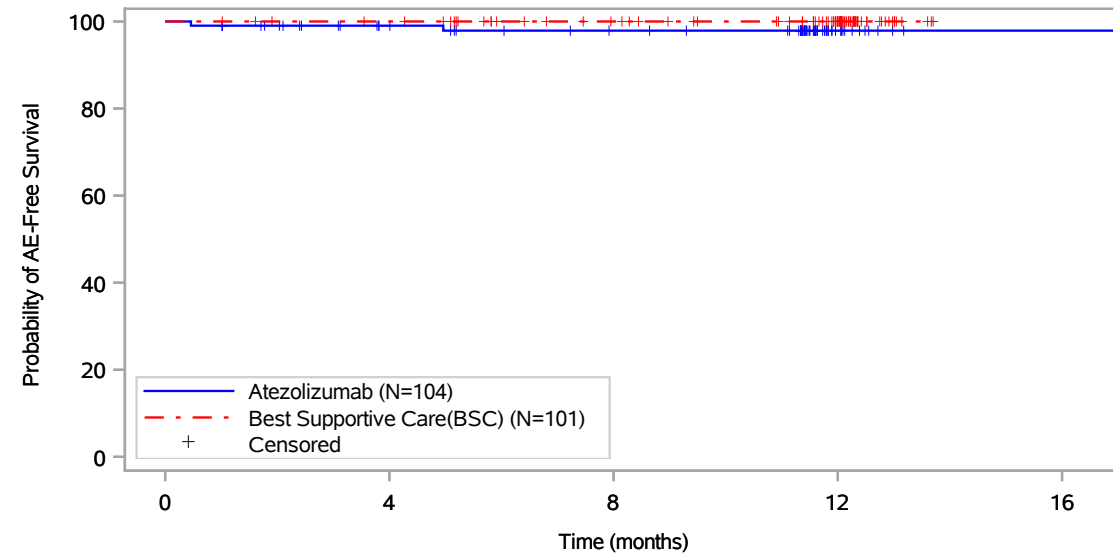
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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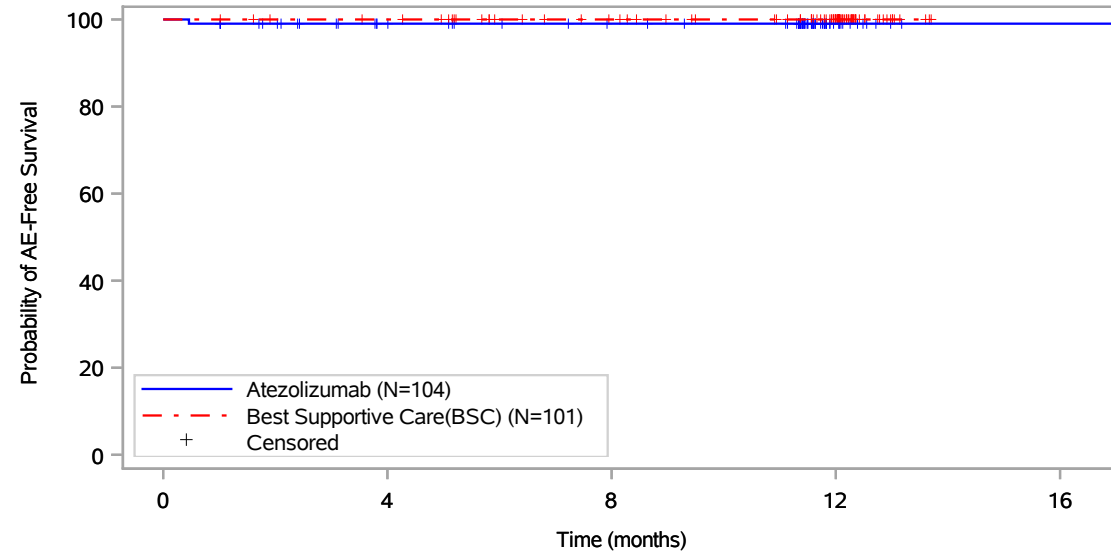
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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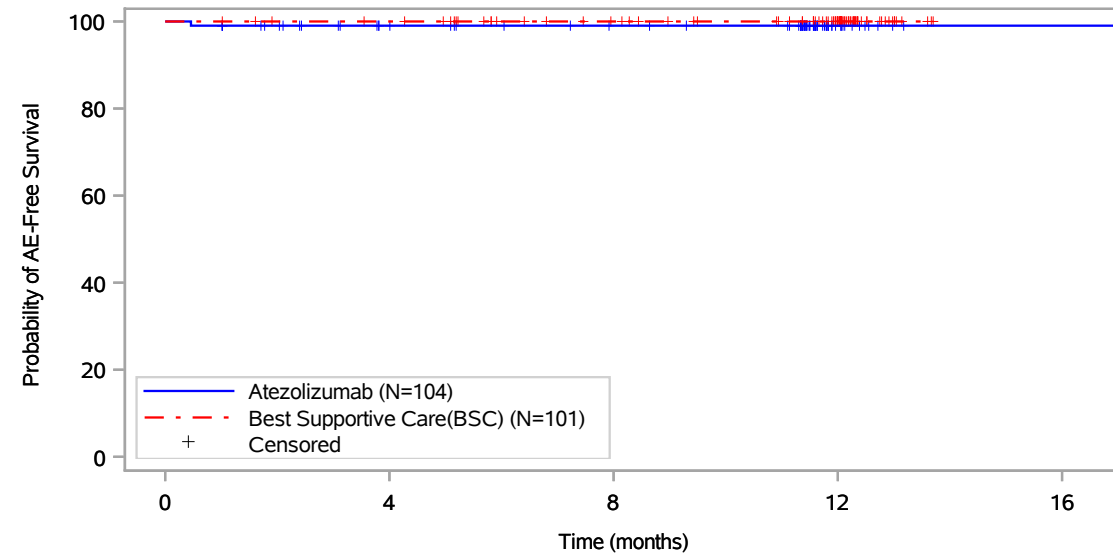
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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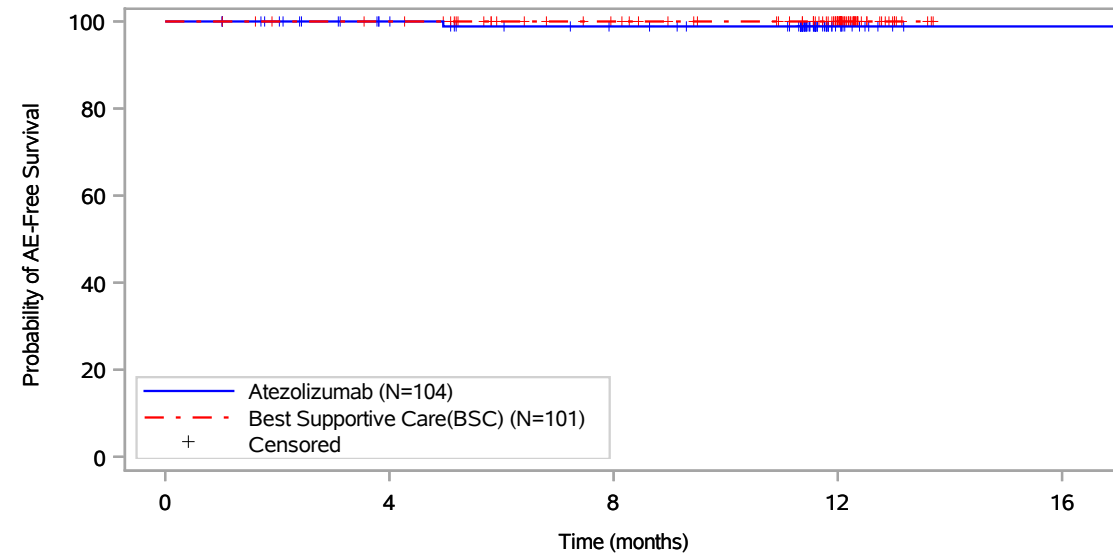
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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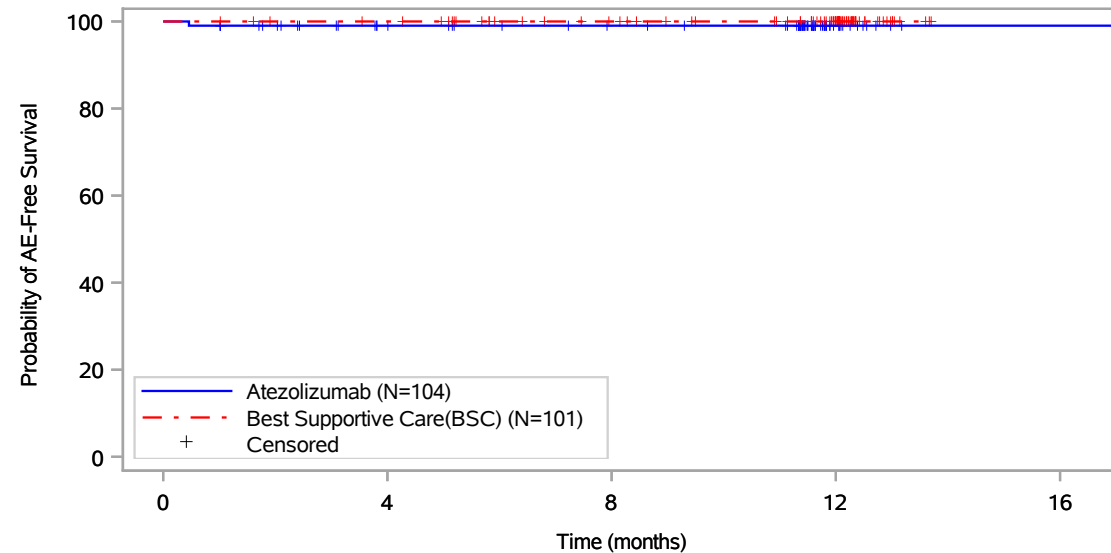
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Endocrine disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..FS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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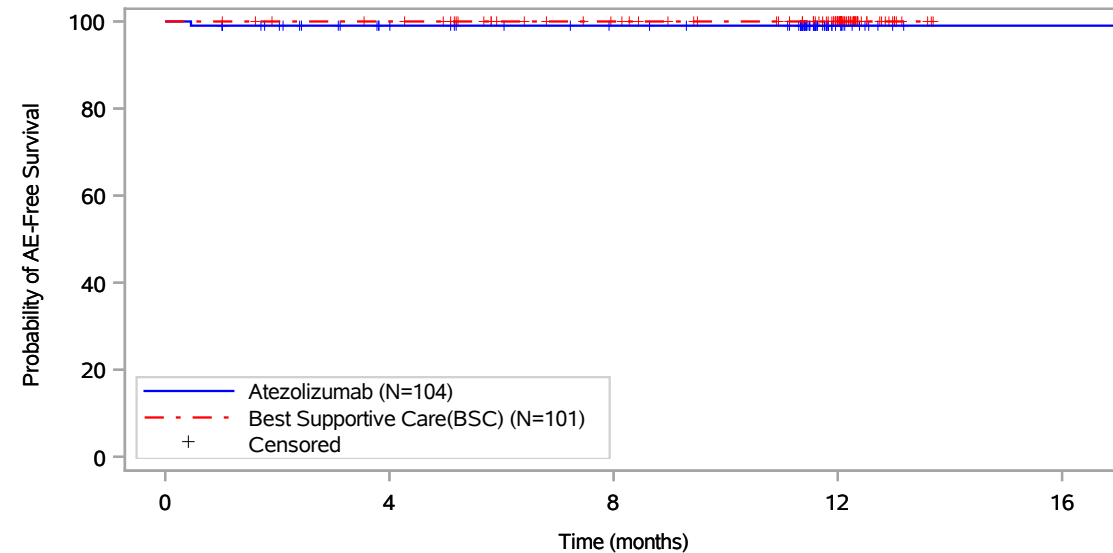
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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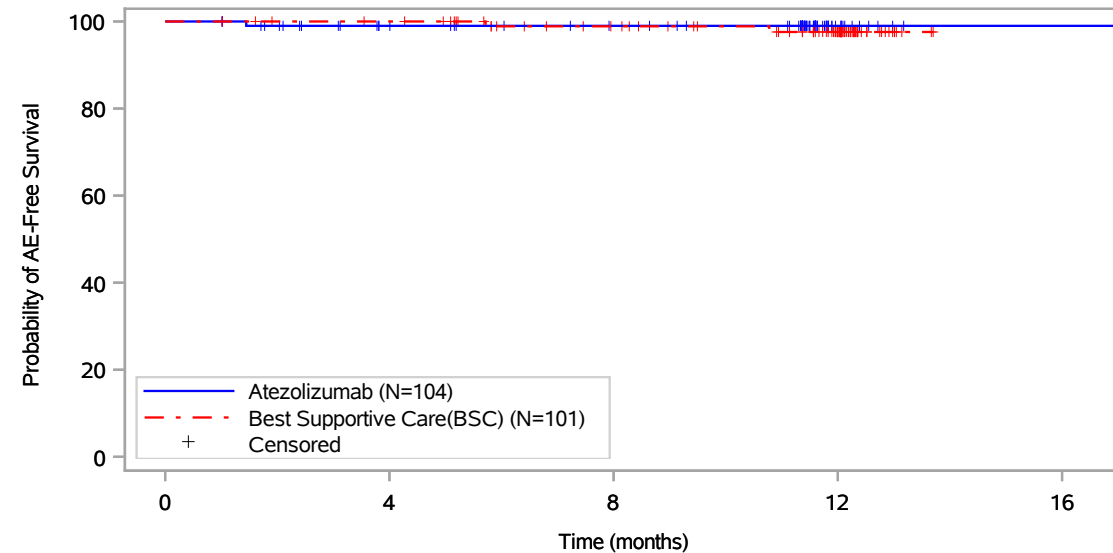
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Eye disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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13DEC2021 21:07

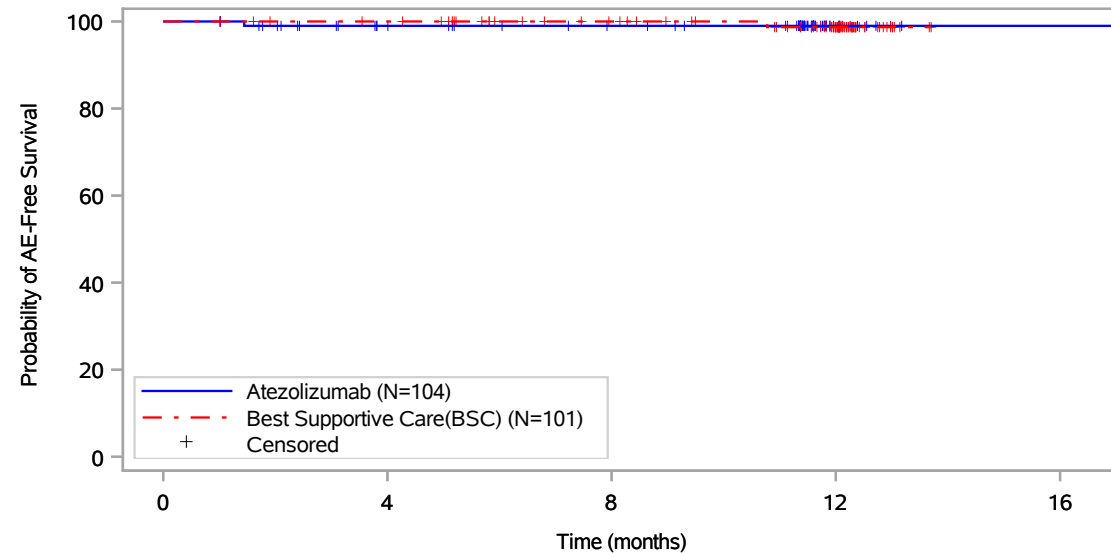
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Eye disorders, Cataract



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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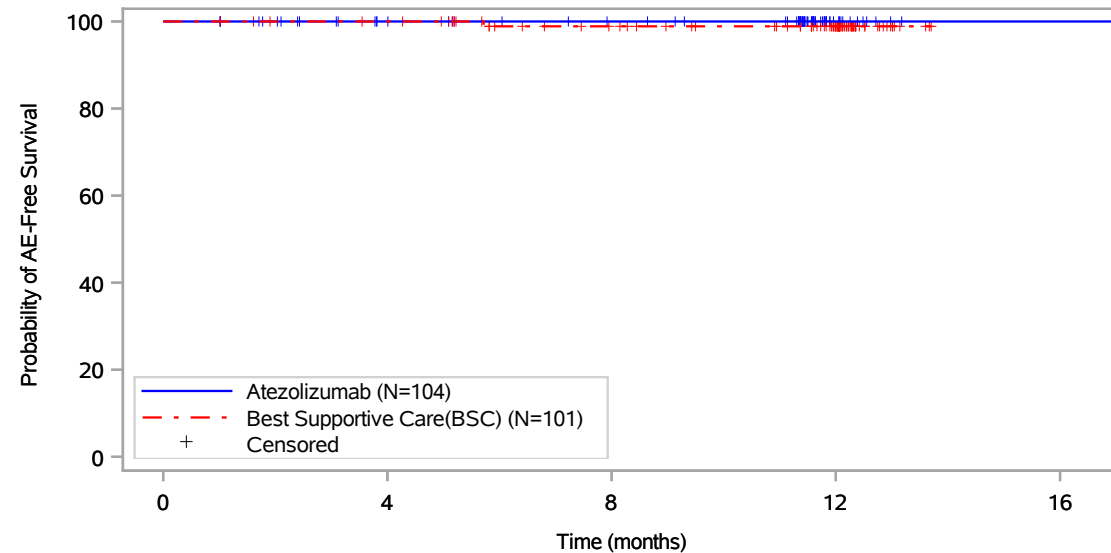
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Eye disorders, Vitreous haemorrhage



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..FS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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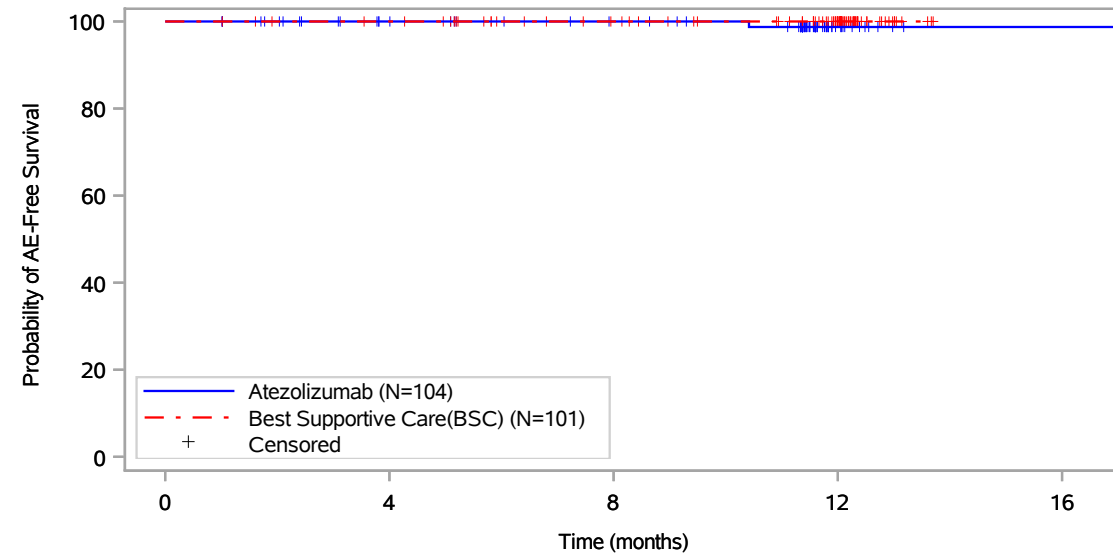
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Gastrointestinal disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..FS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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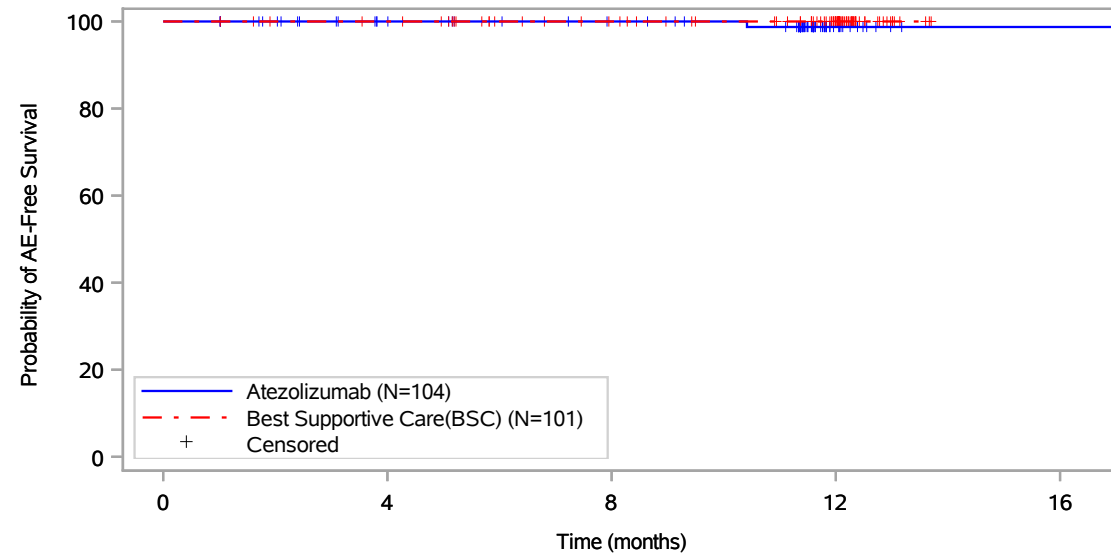
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Colitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

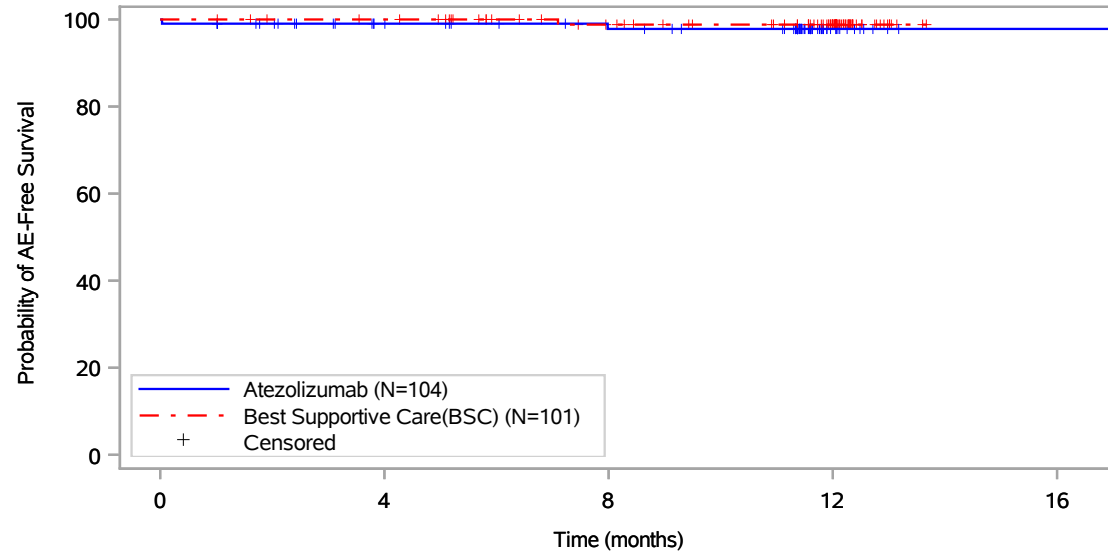
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

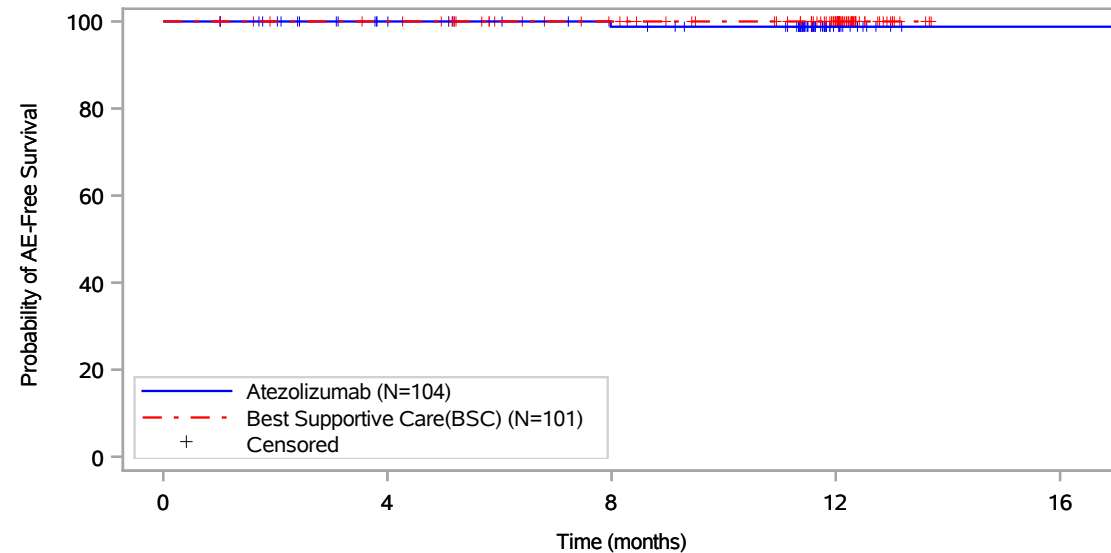
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

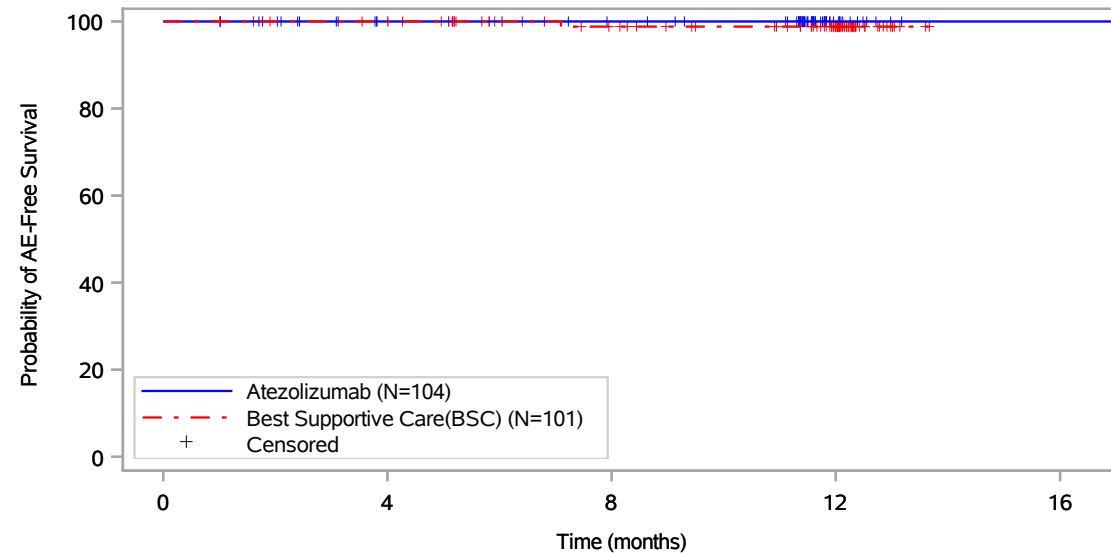
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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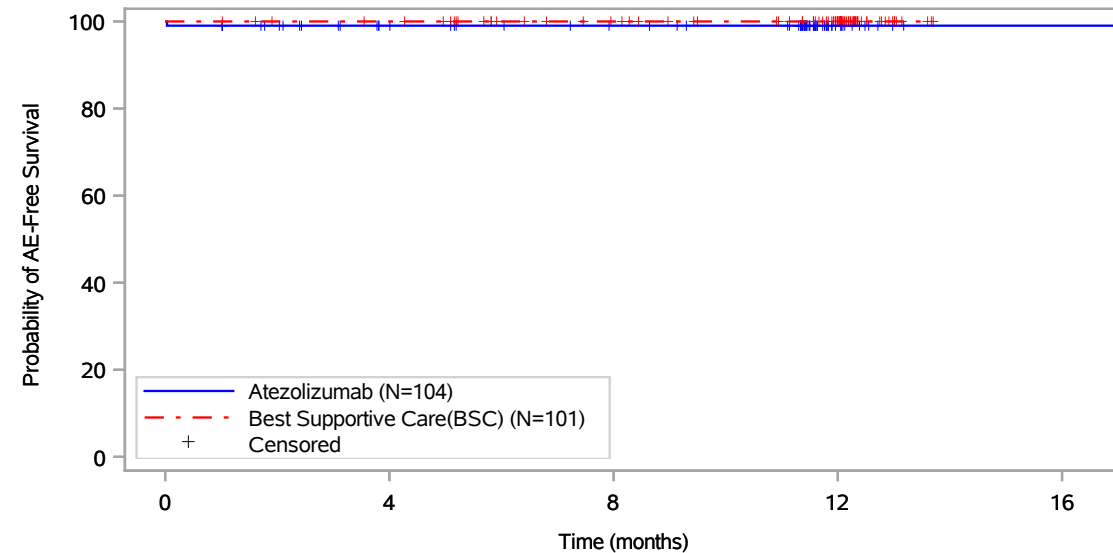
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Pyrexia



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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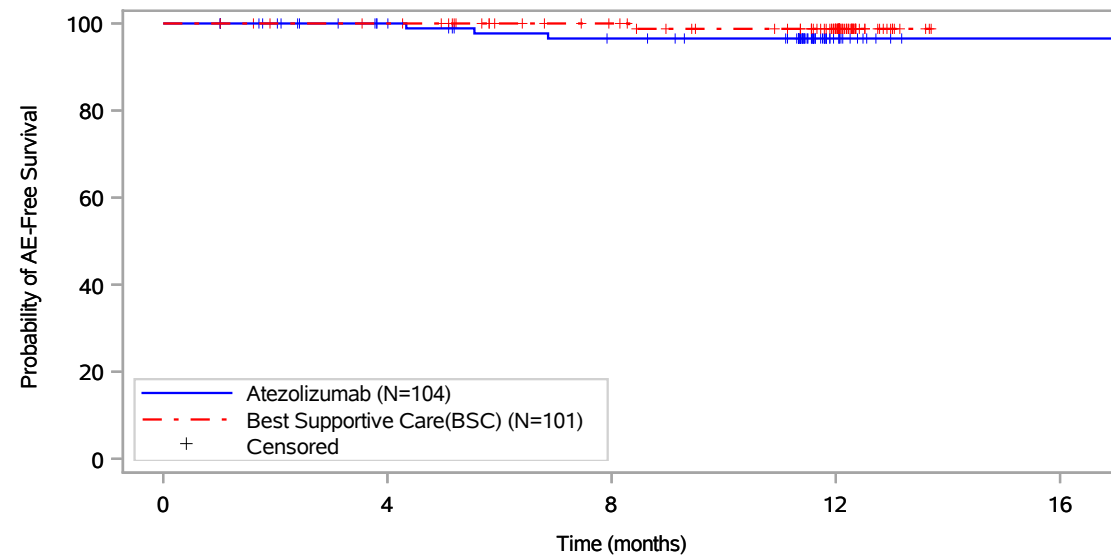
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	19	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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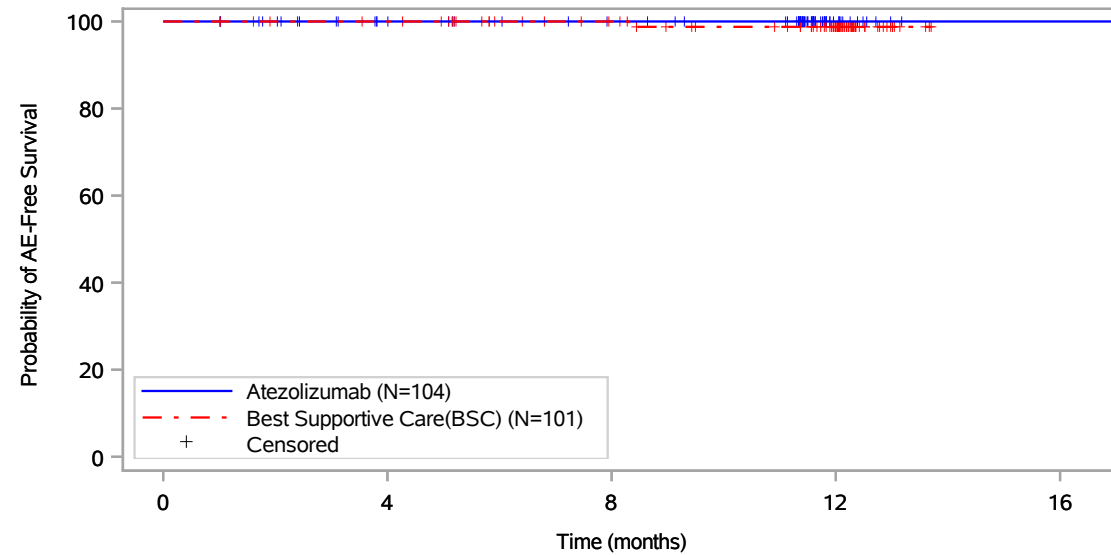
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Cholestasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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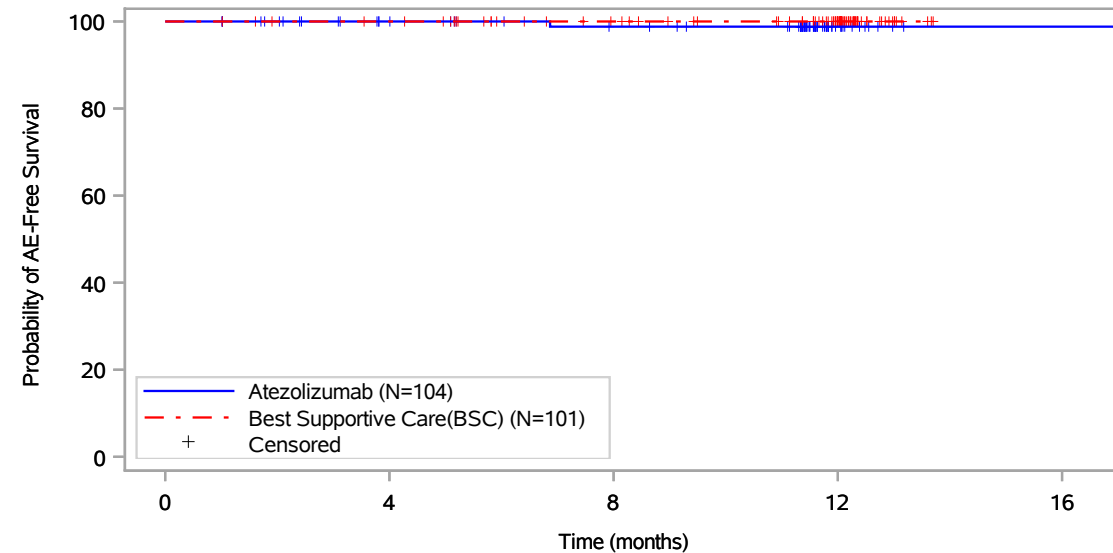
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Drug-induced liver injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

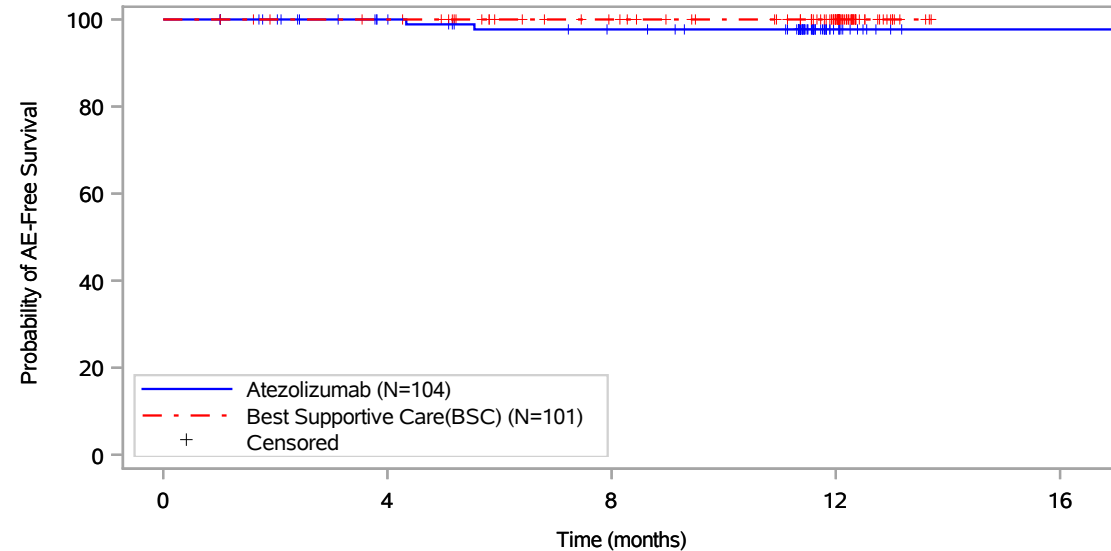
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



Patients at risk					
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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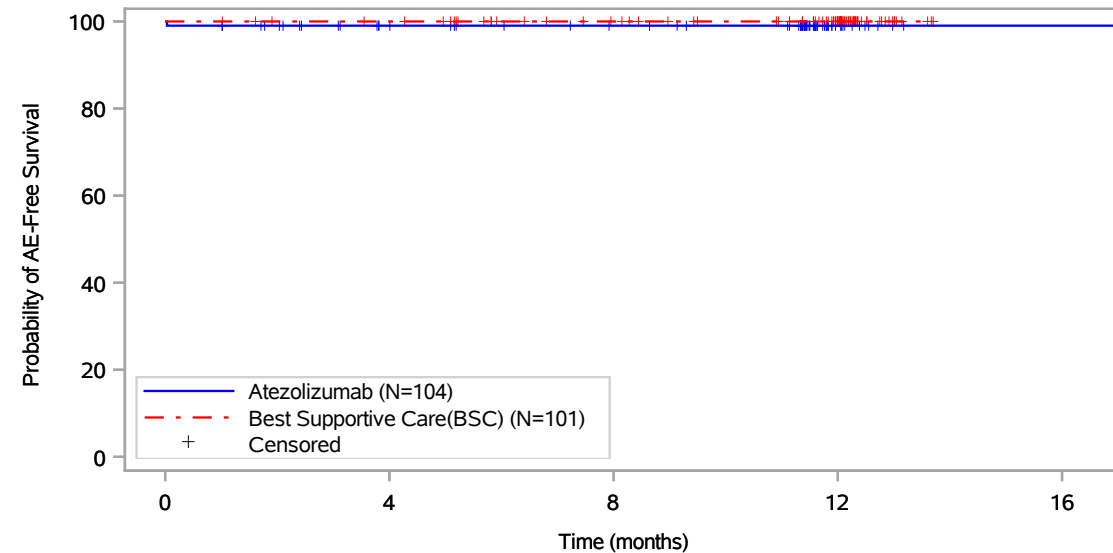
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Immune system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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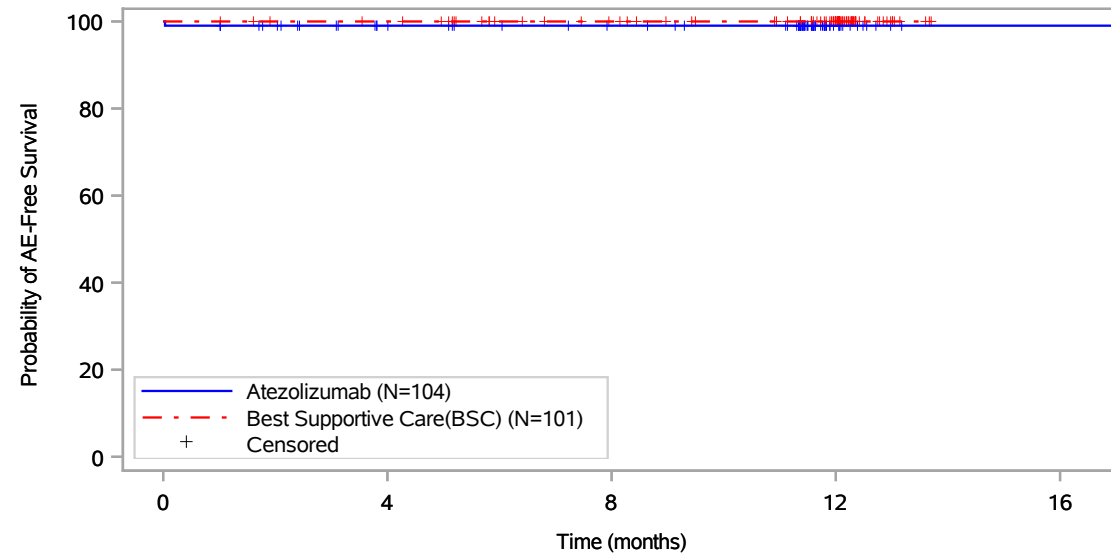
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Immune system disorders, Hypersensitivity



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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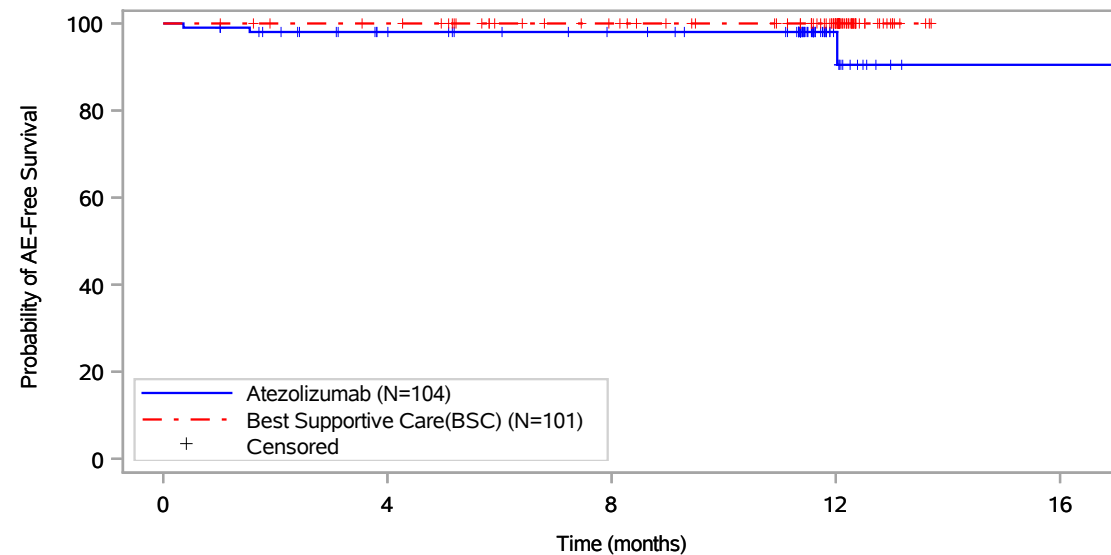
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Infections and infestations, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	89	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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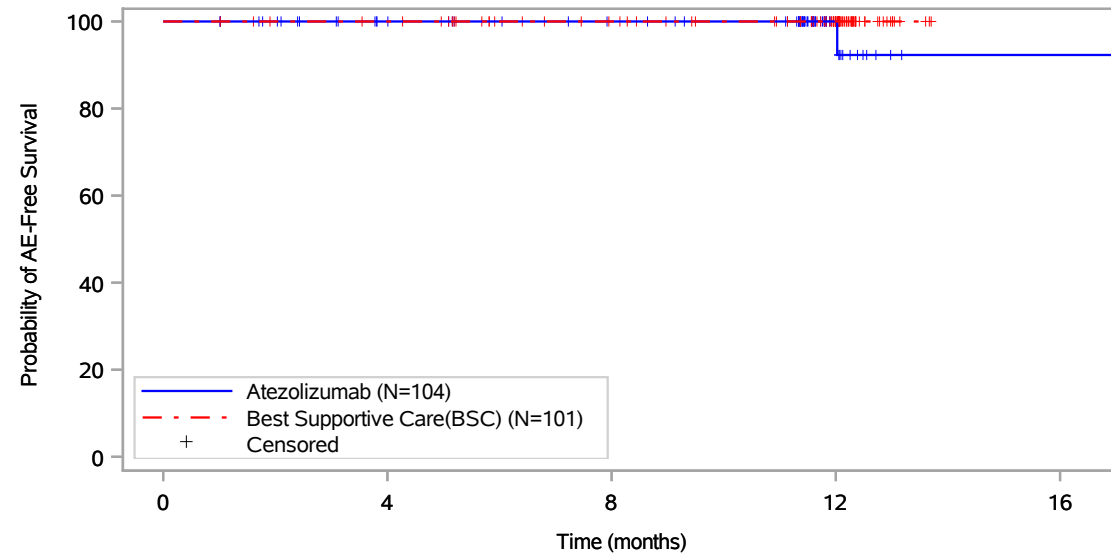
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Infections and infestations, Cellulitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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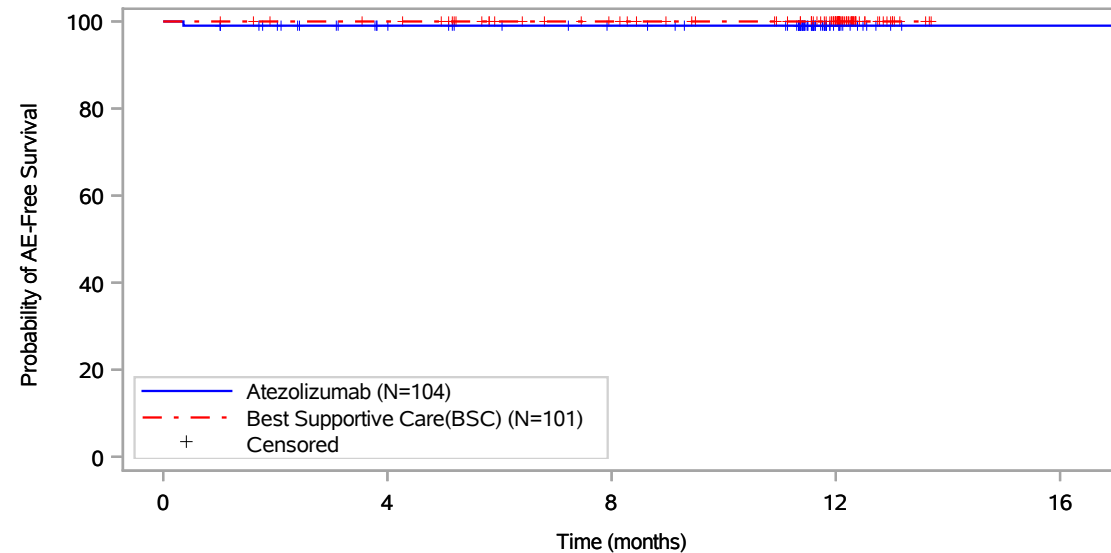
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Infections and infestations, Encephalitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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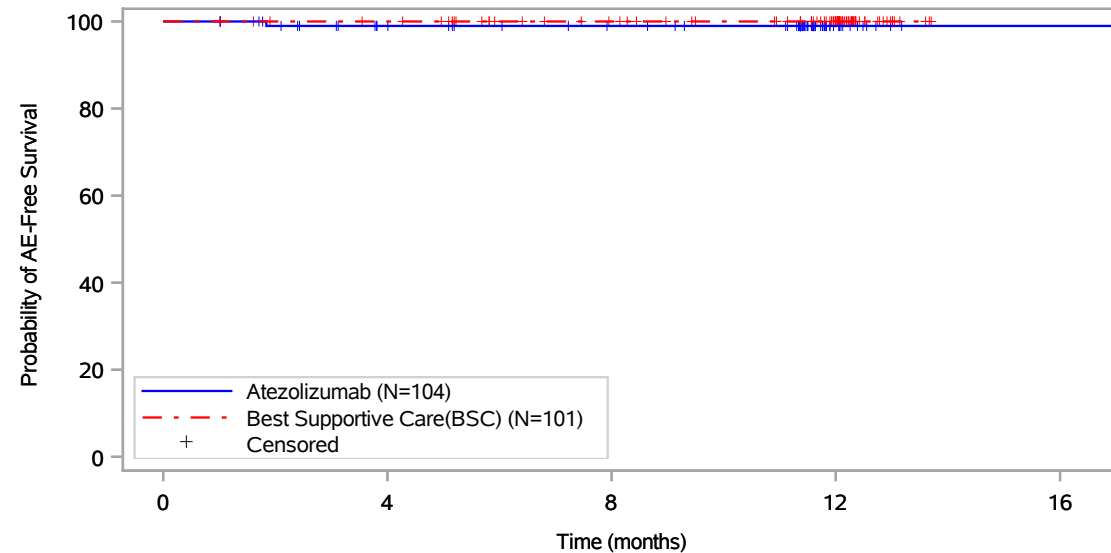
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Infections and infestations, Kidney infection



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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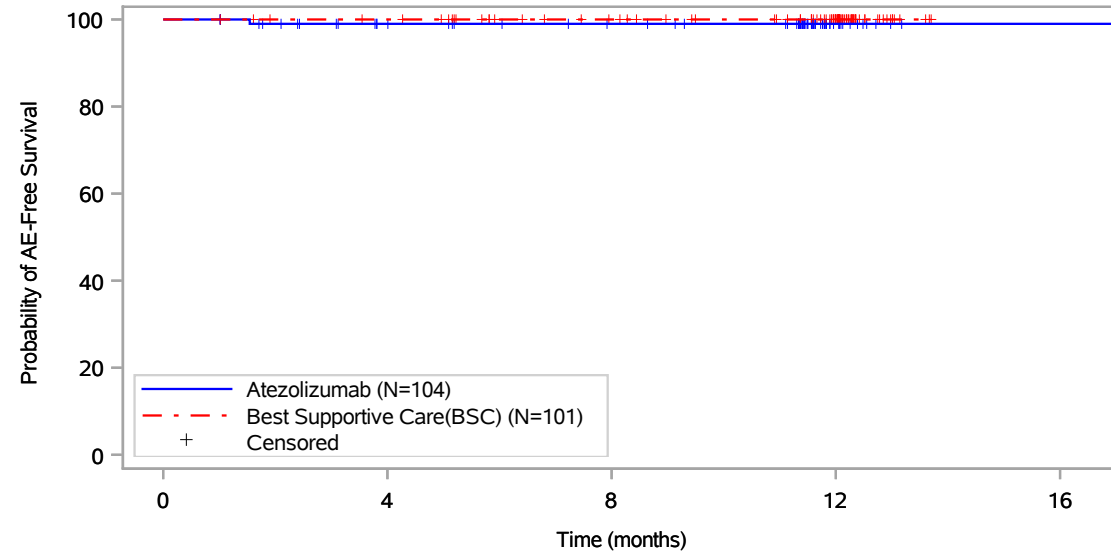
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Infections and infestations, Meningitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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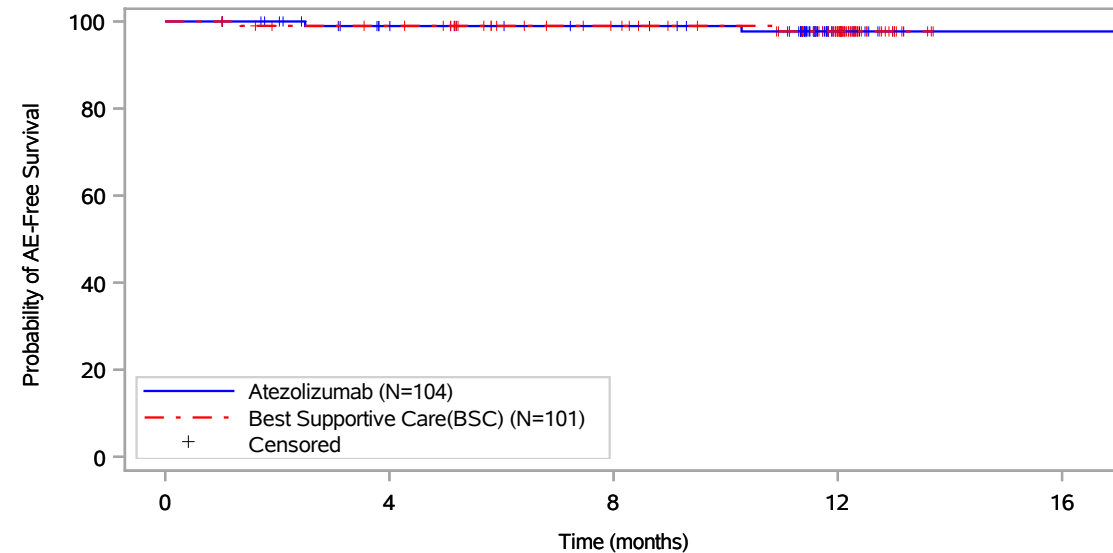
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Investigations, All



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

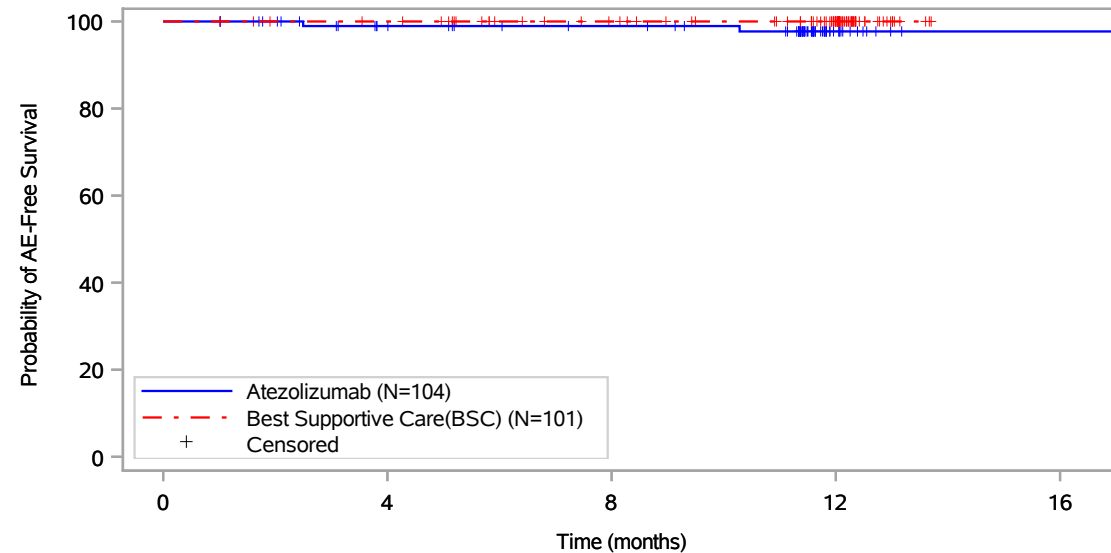
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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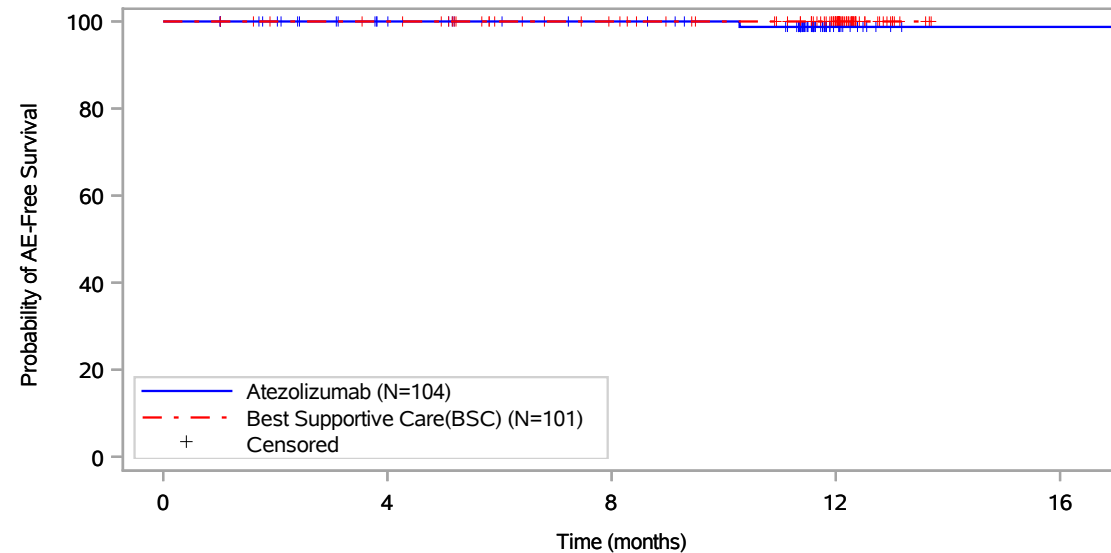
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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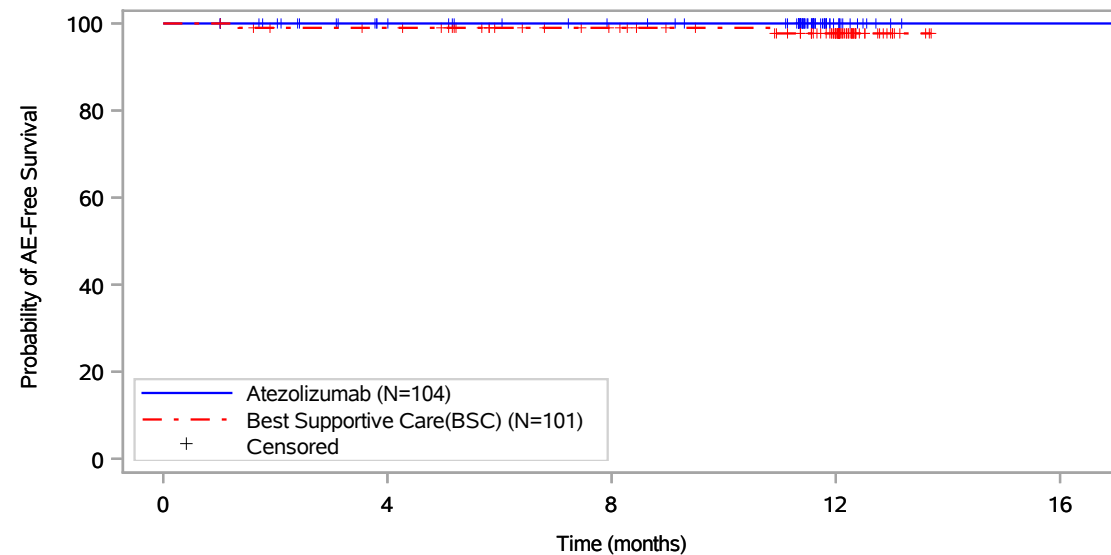
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Investigations, Neutrophil count decreased



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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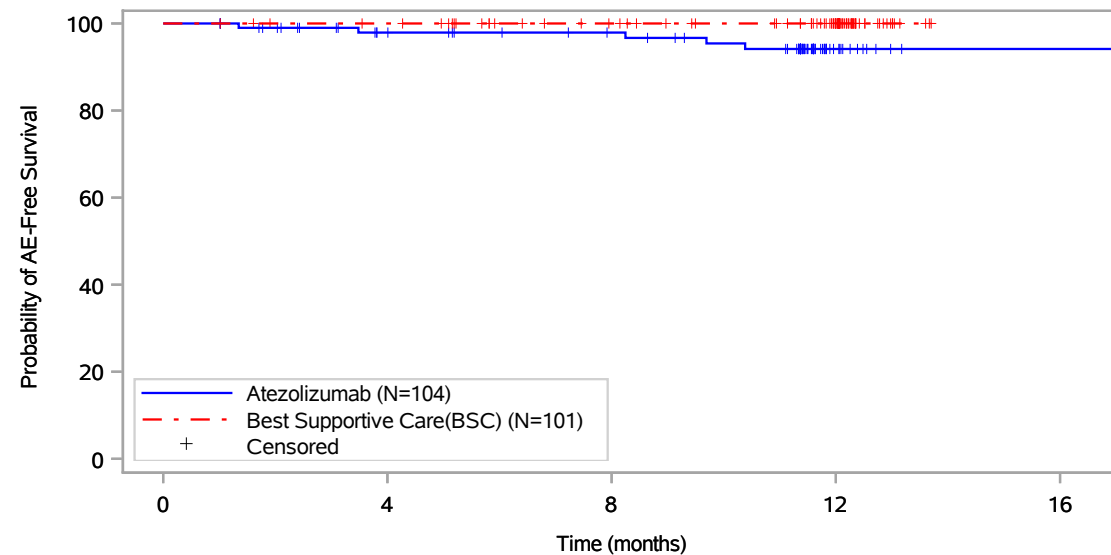
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk					
Atezolizumab (N=104)	104	87	80	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	87	98
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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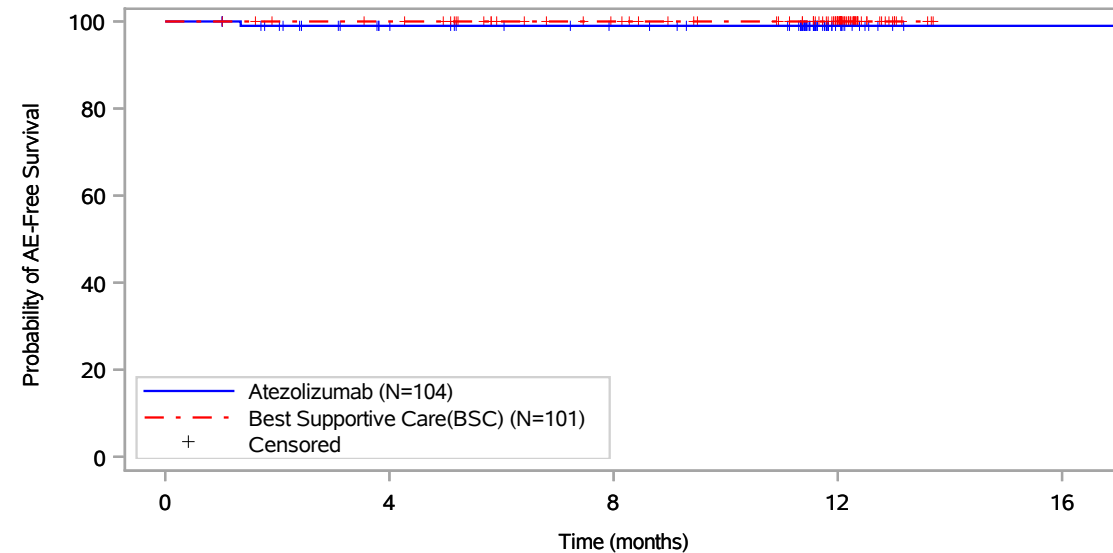
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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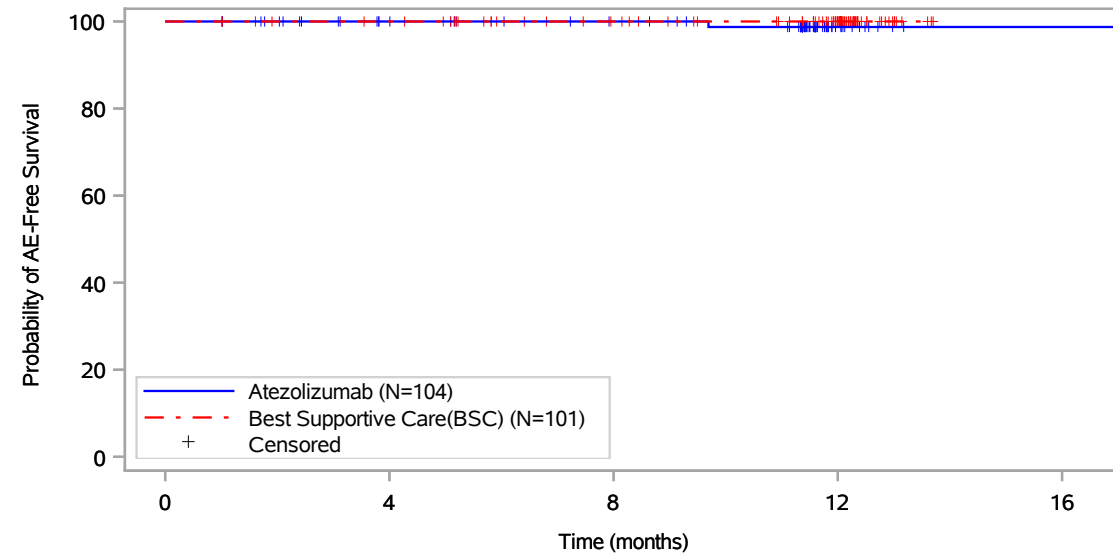
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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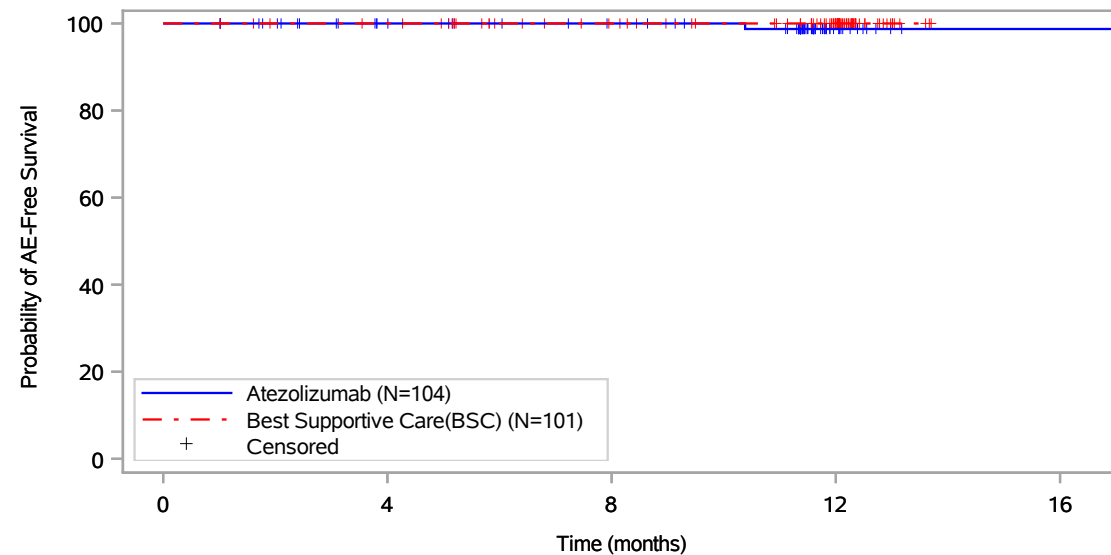
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

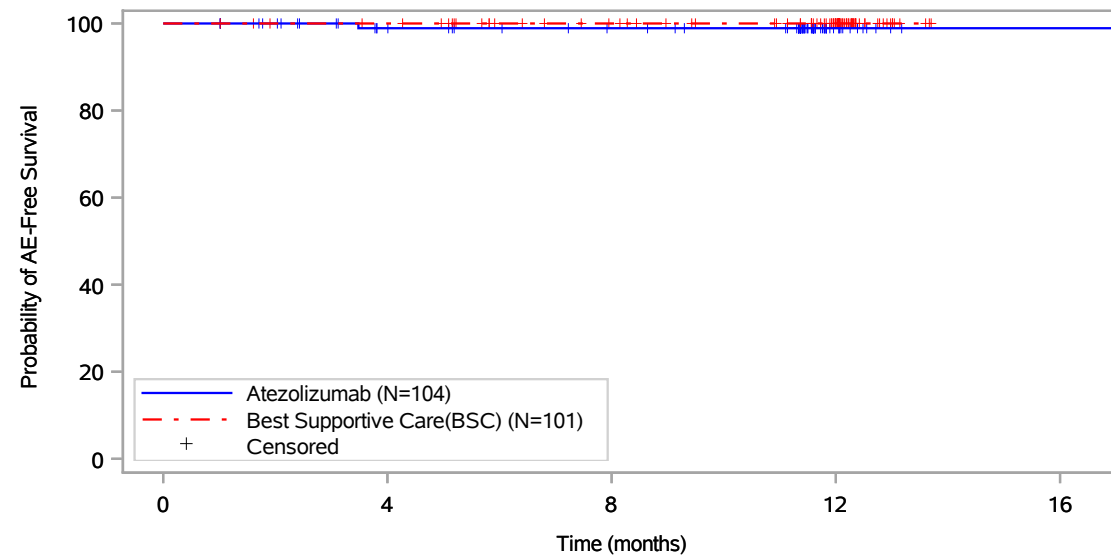
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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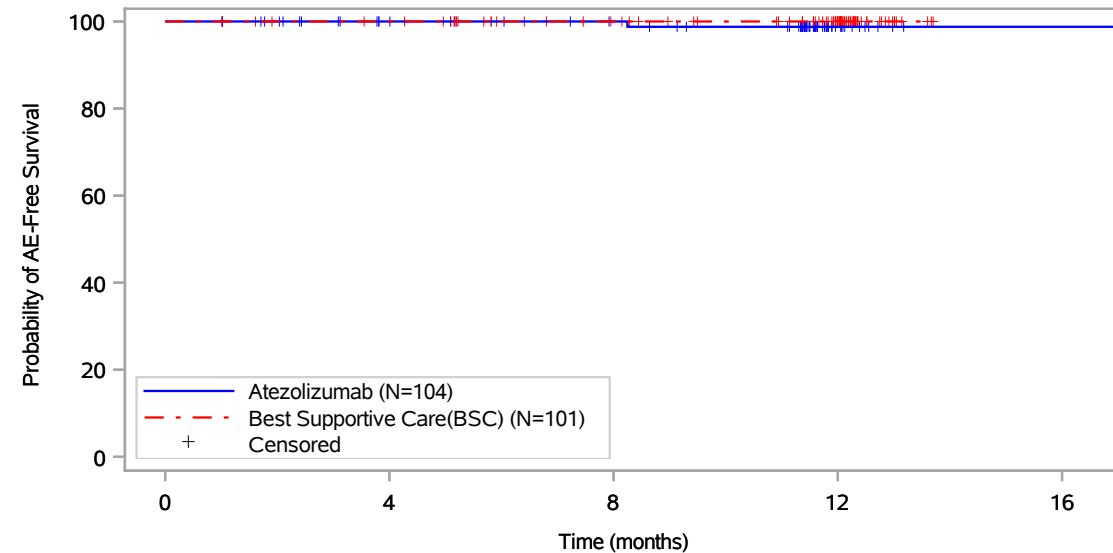
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

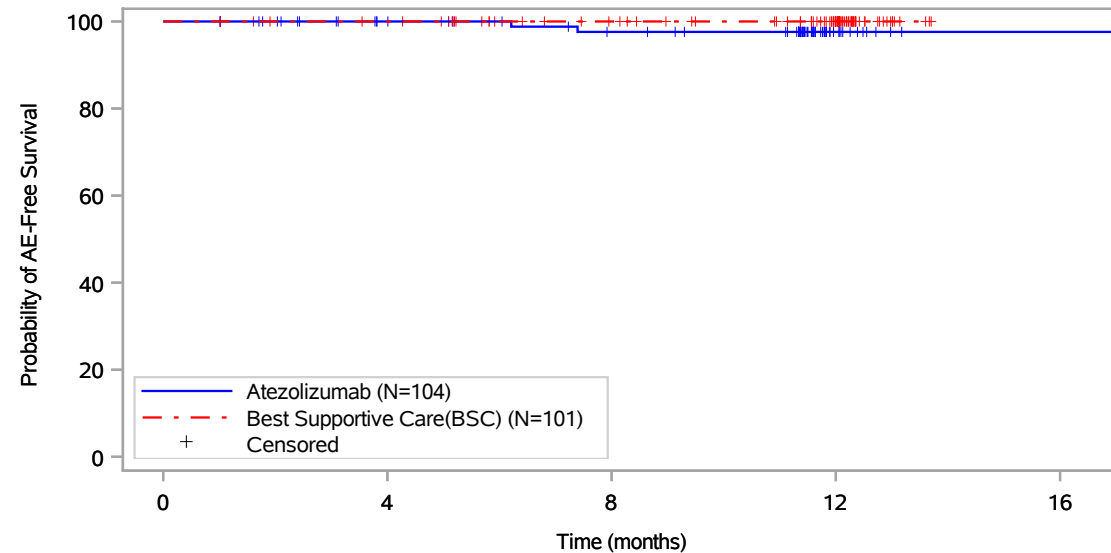
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	80	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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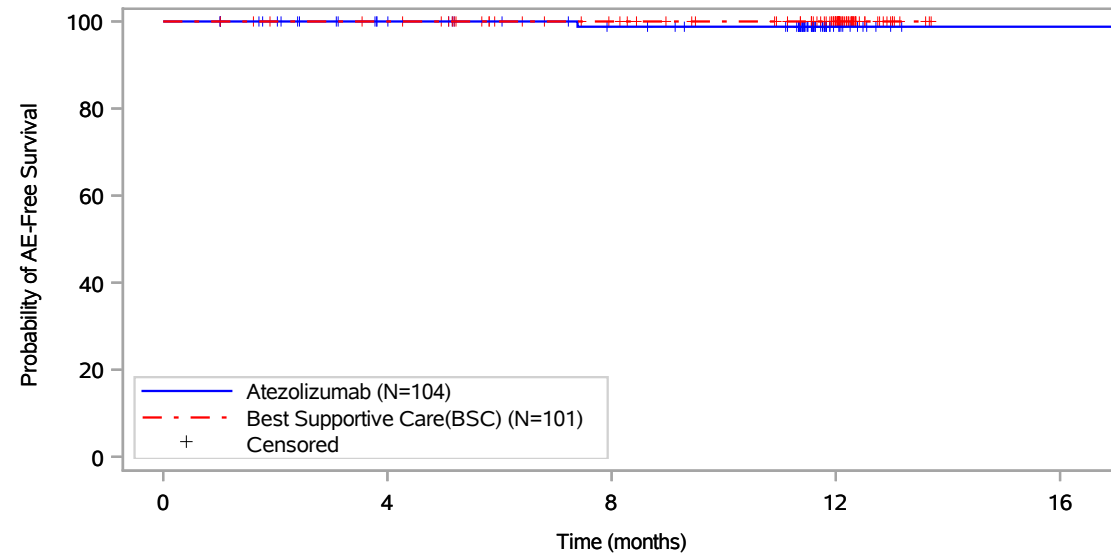
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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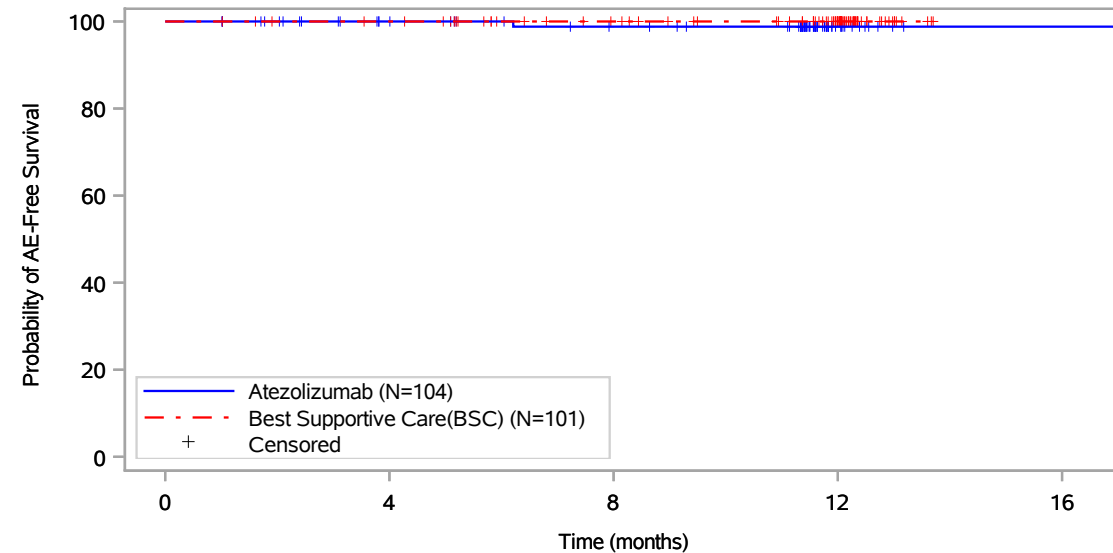
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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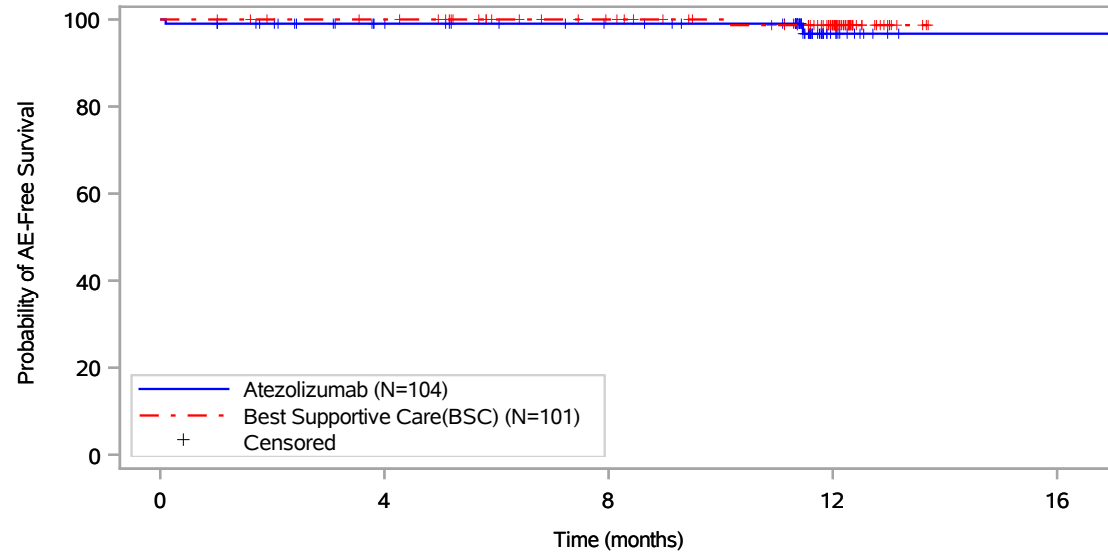
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk					
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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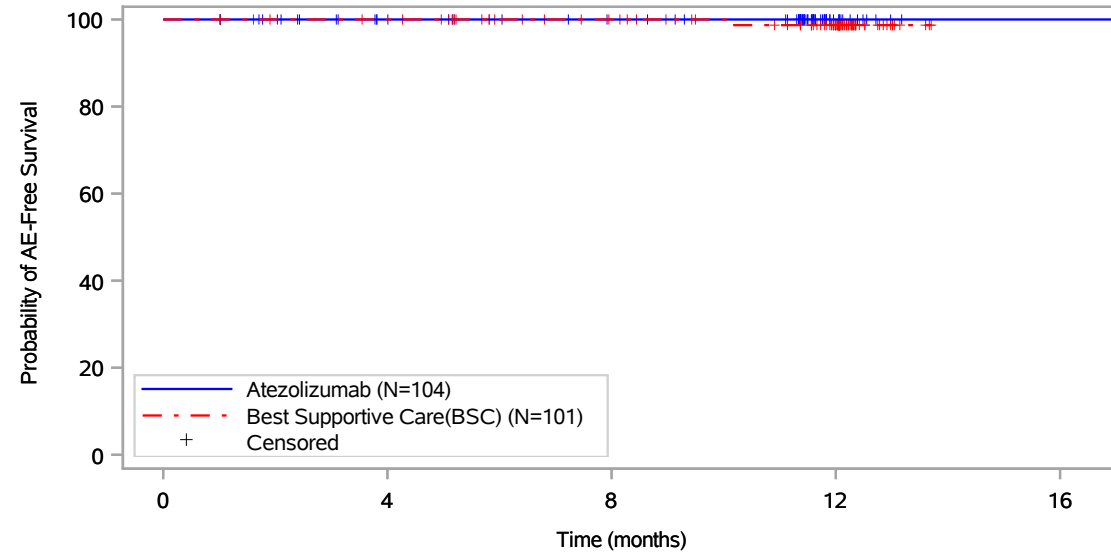
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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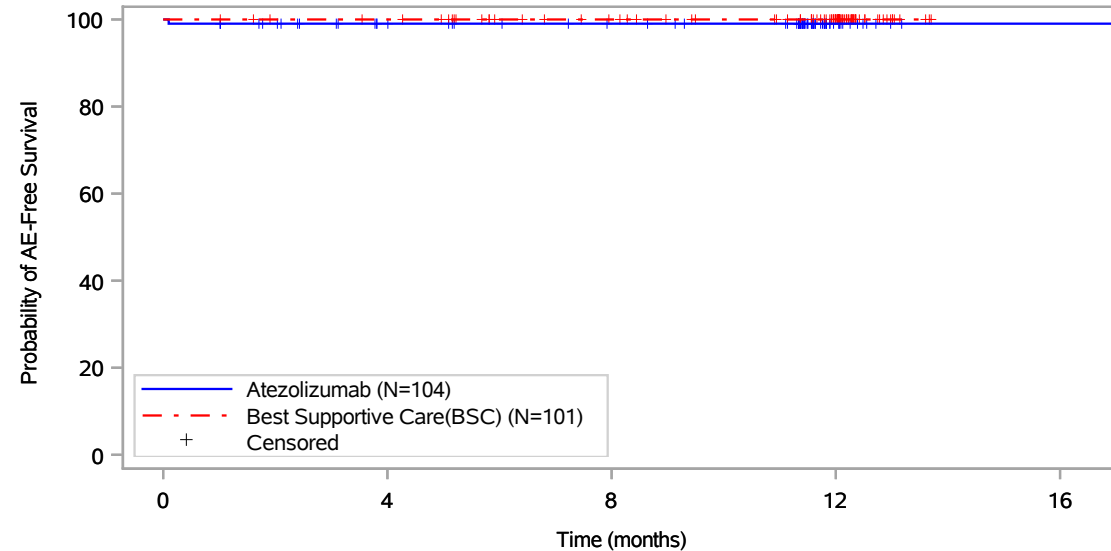
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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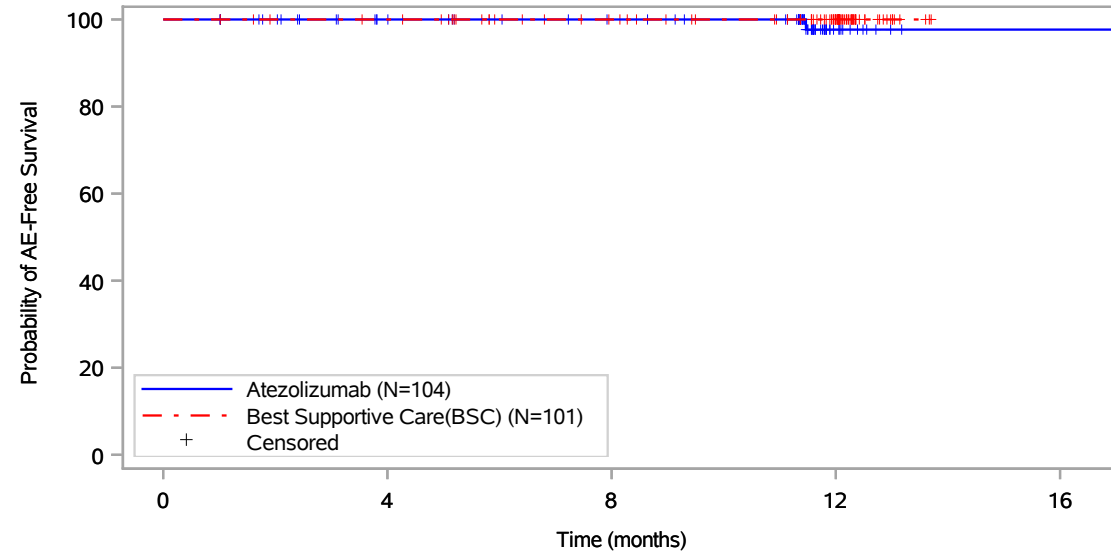
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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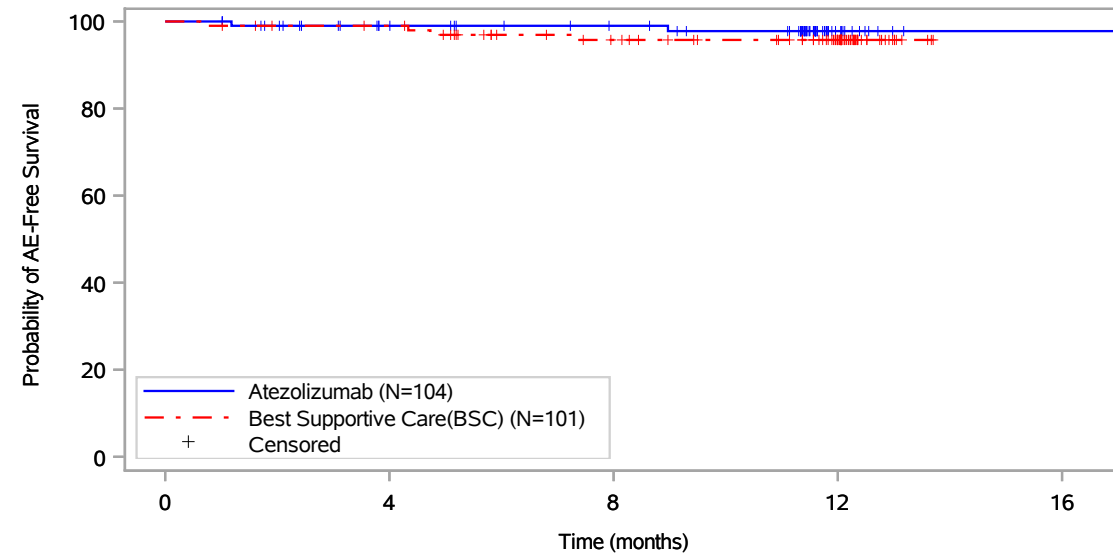
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	80	53	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	17	44	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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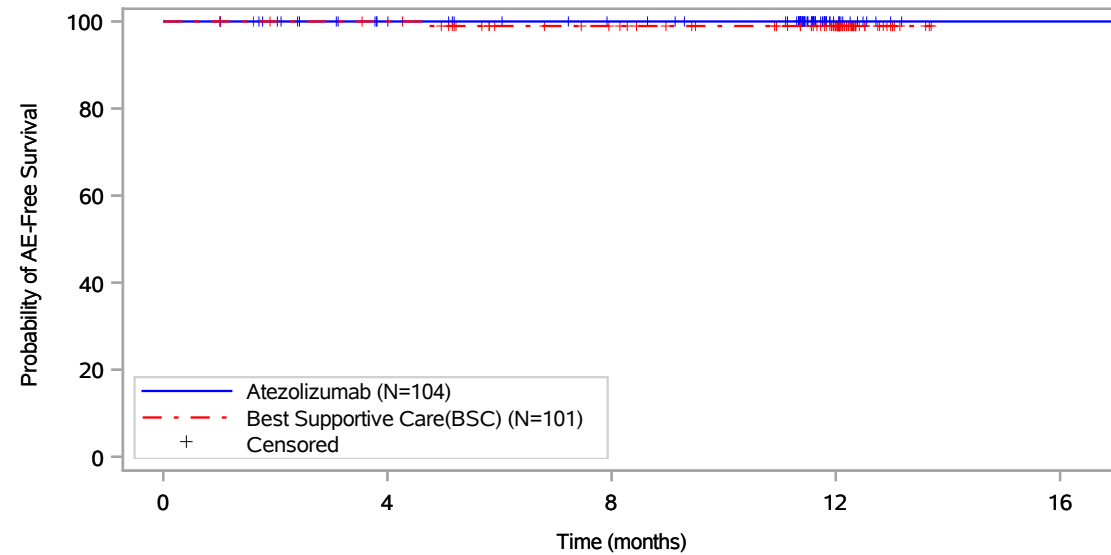
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Brain oedema



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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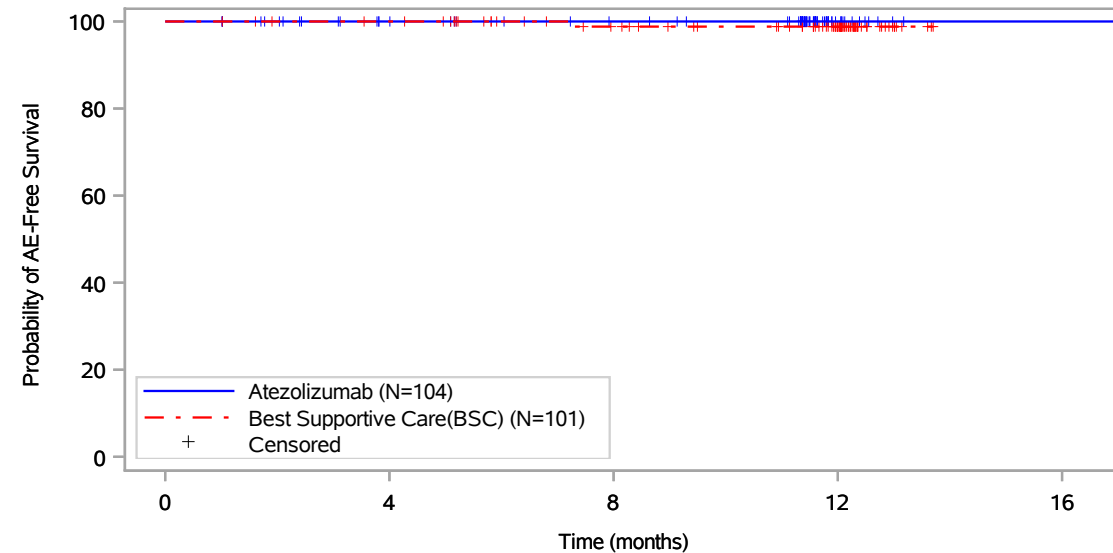
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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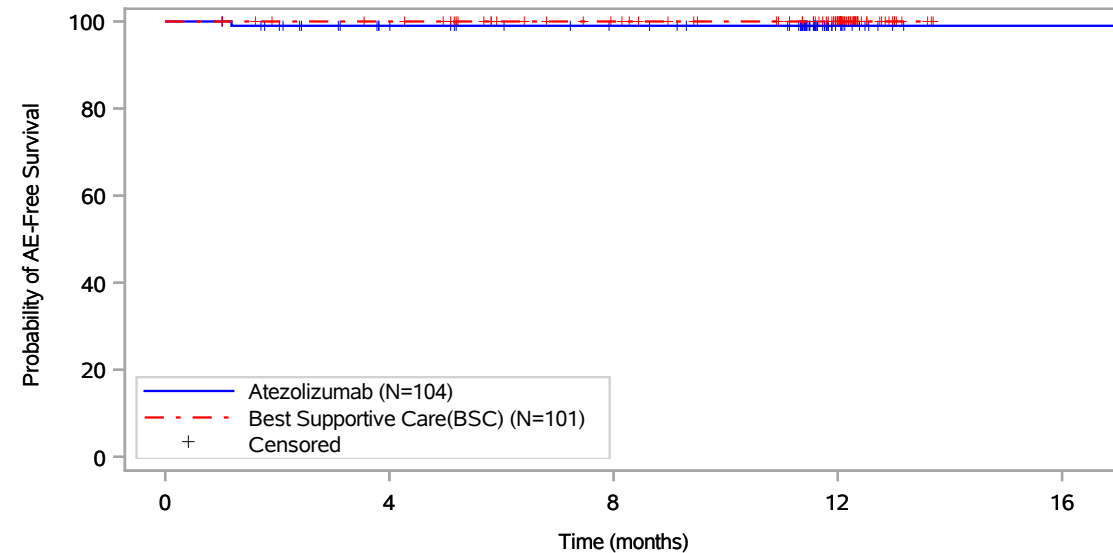
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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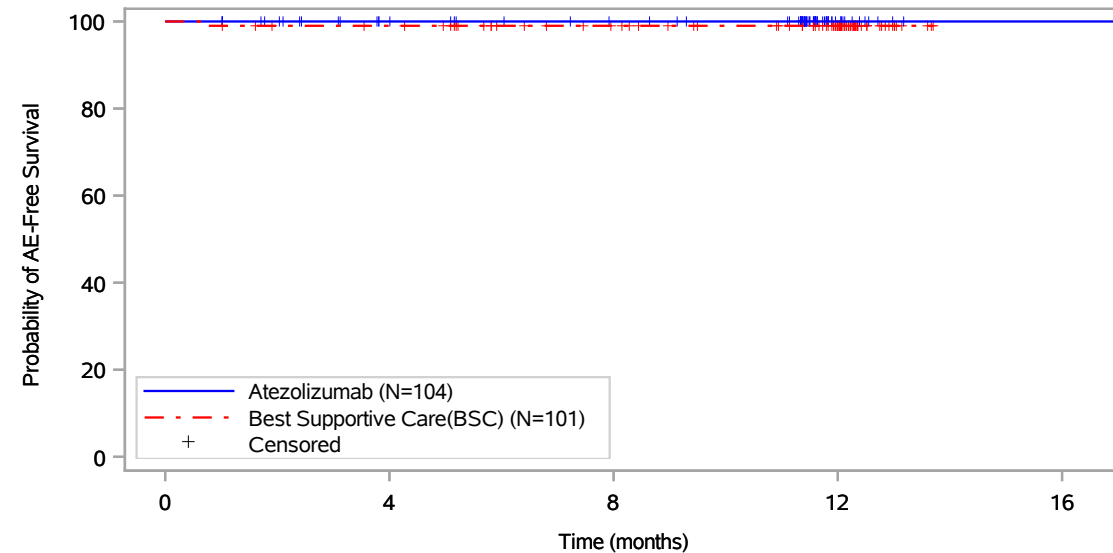
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Paraesthesia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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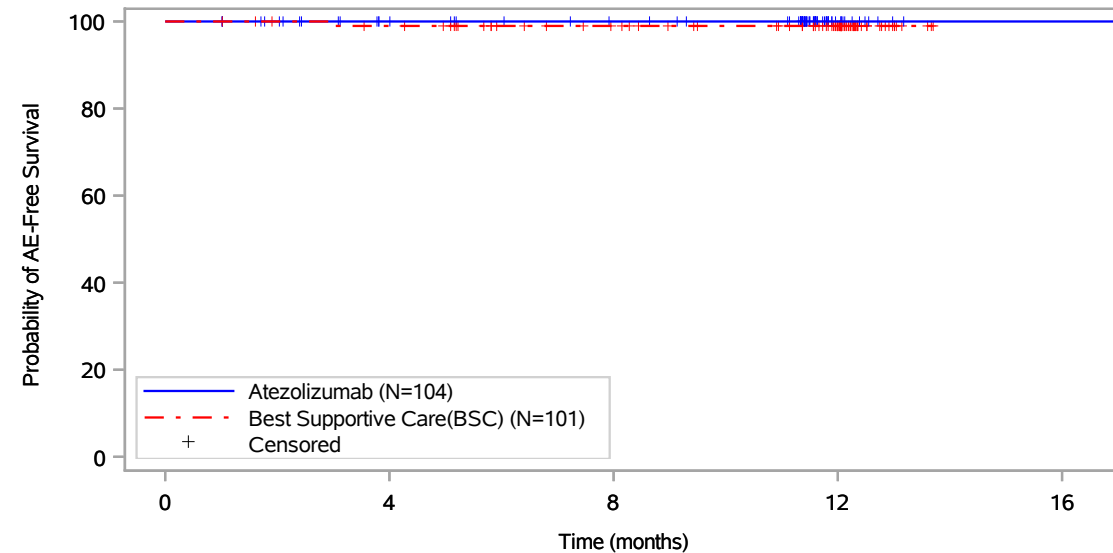
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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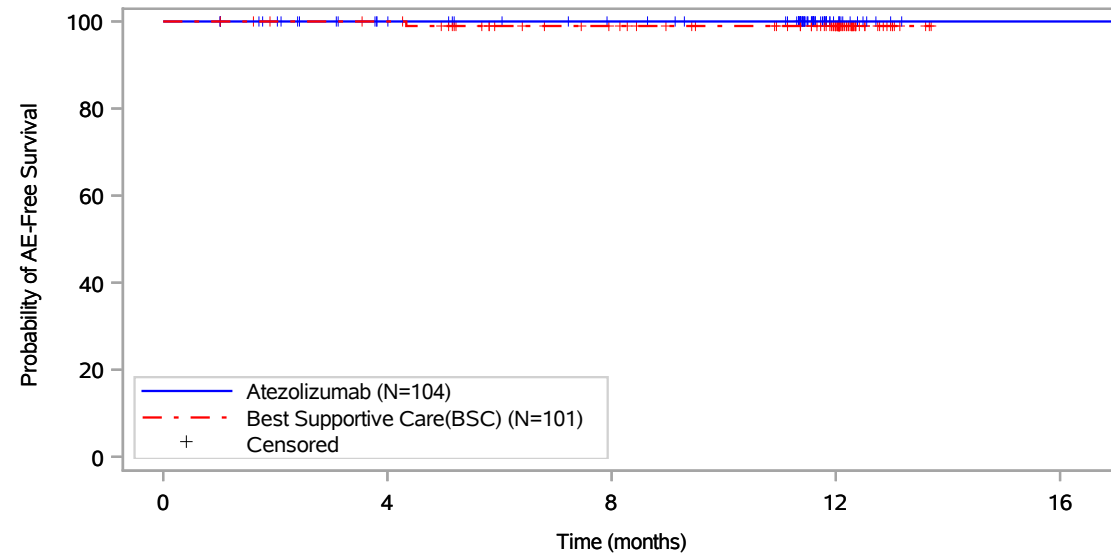
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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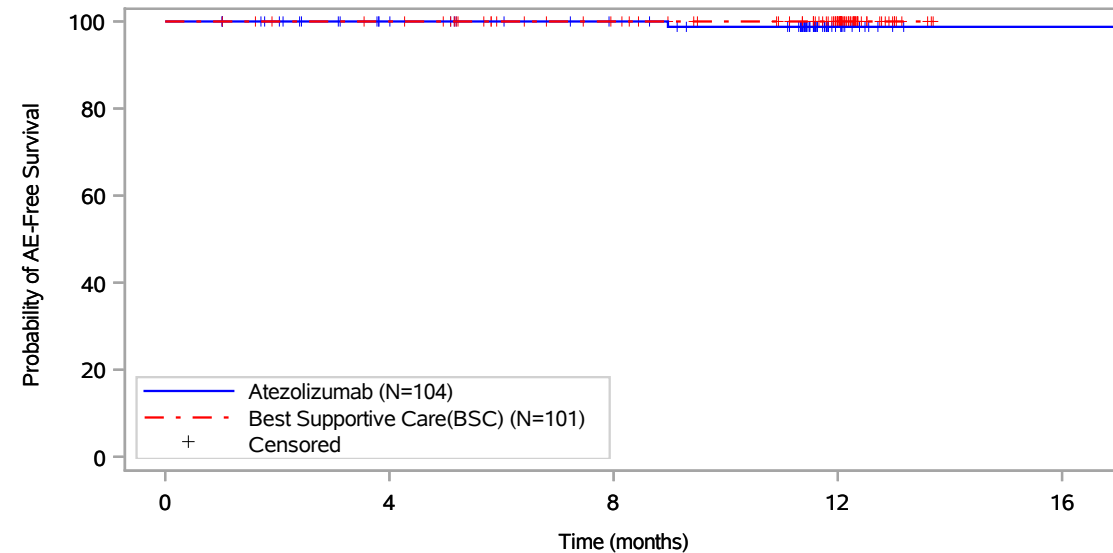
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Nervous system disorders, Syncope



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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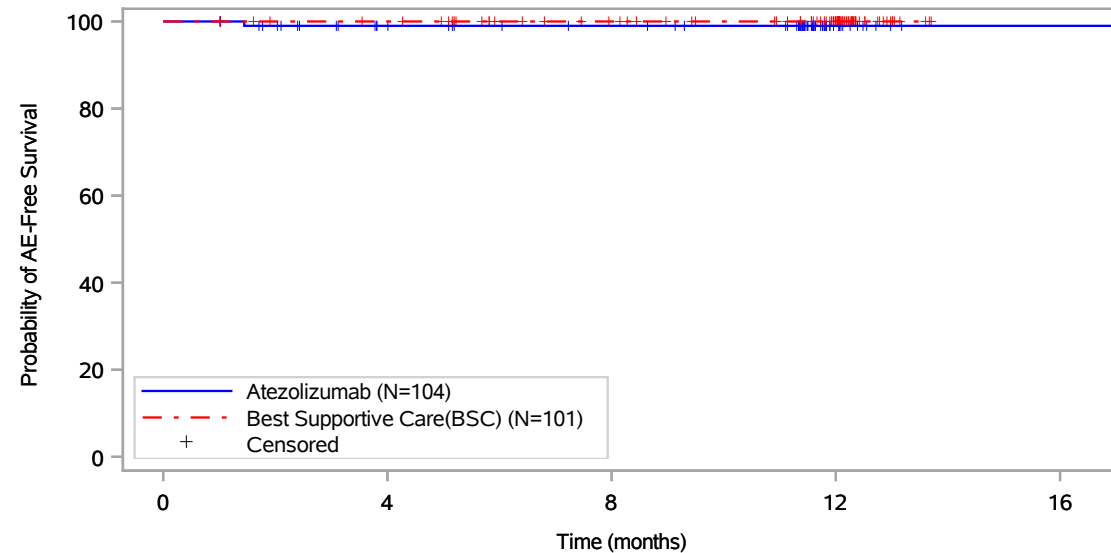
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Renal and urinary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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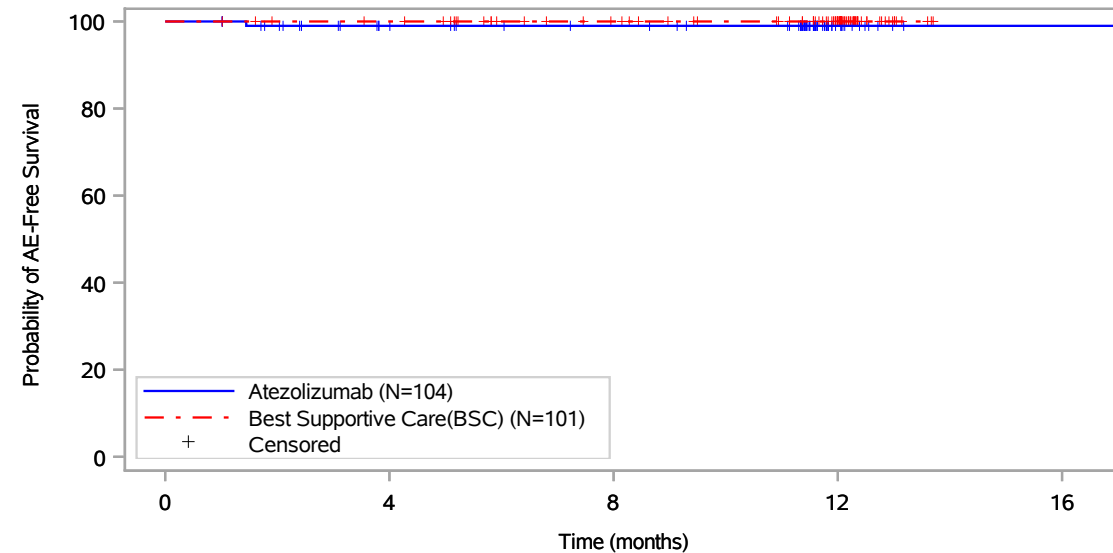
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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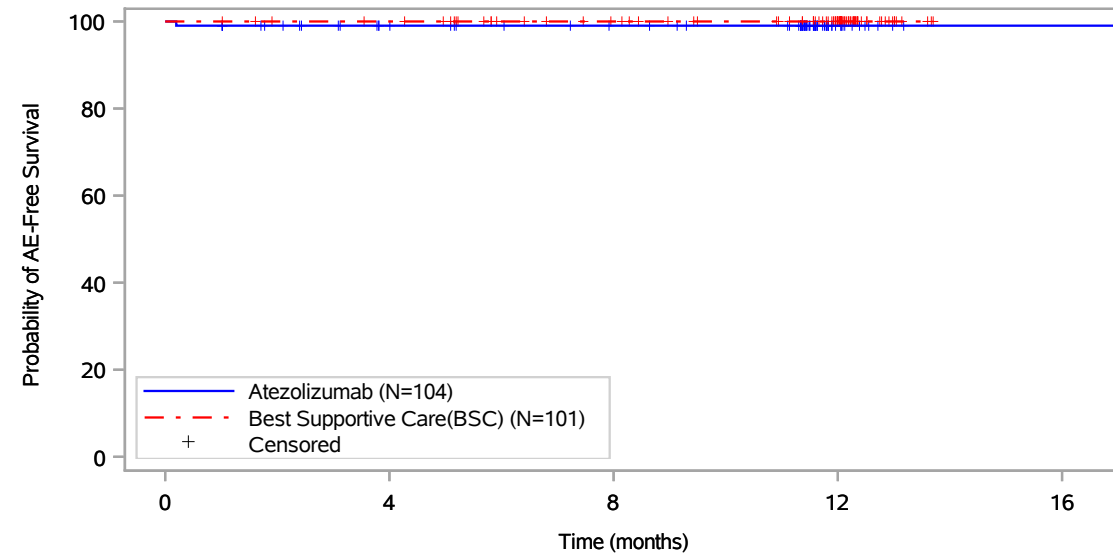
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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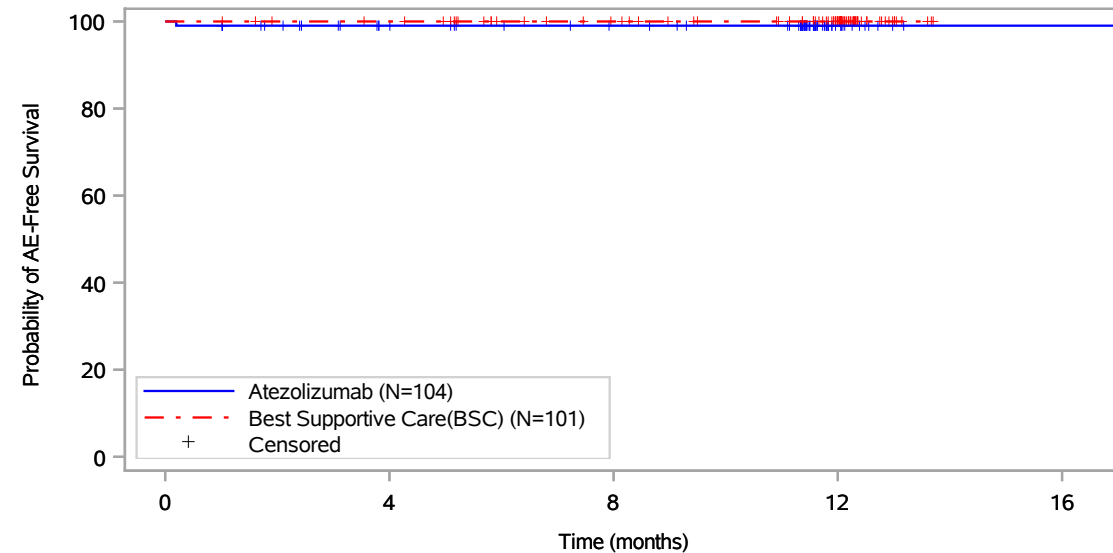
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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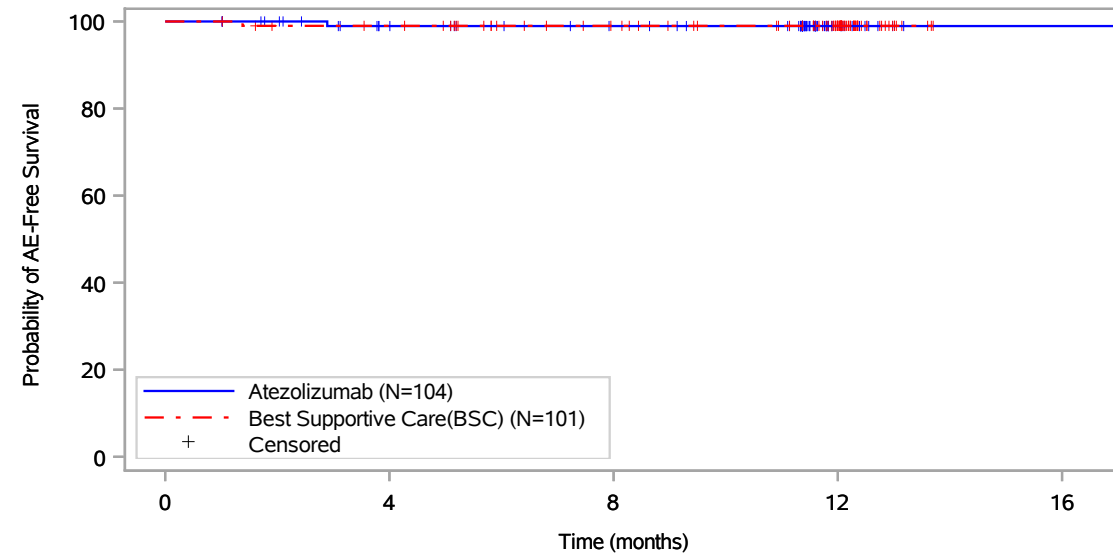
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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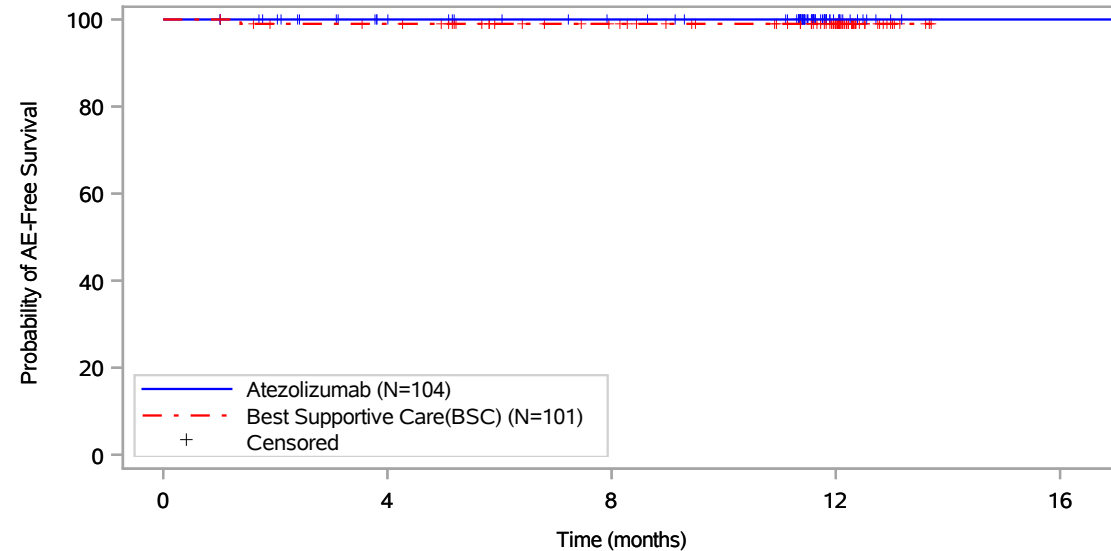
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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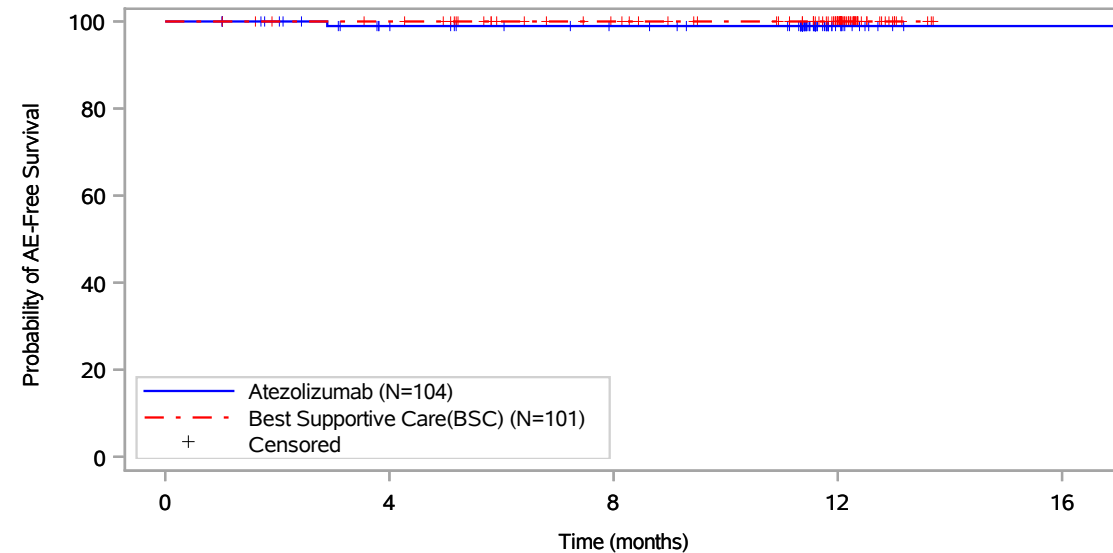
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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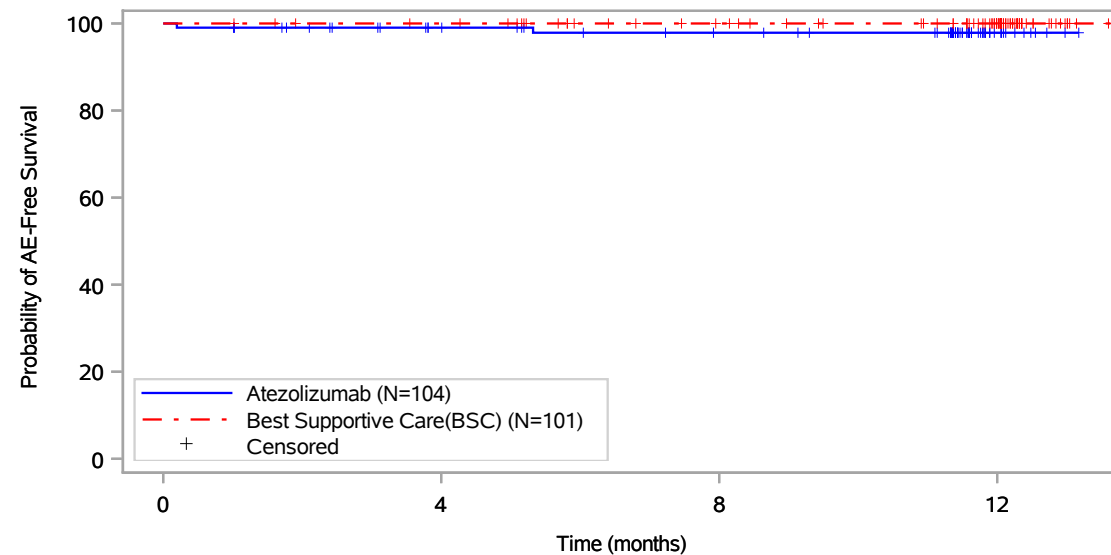
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	89	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	14	21	90
Best Supportive Care(BSC) (N=101)	0	4	18	46

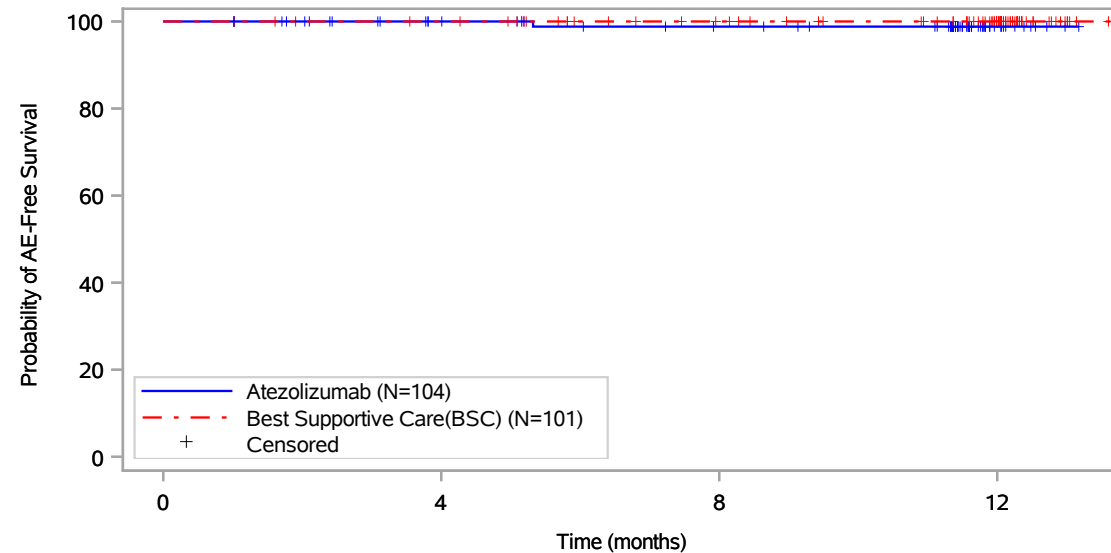
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	89	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	15	22	91
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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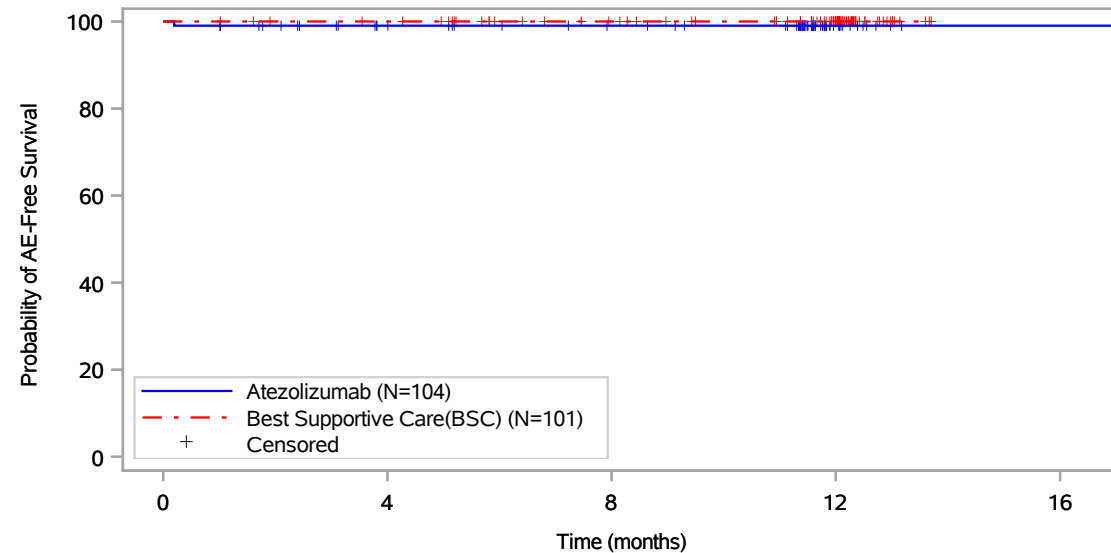
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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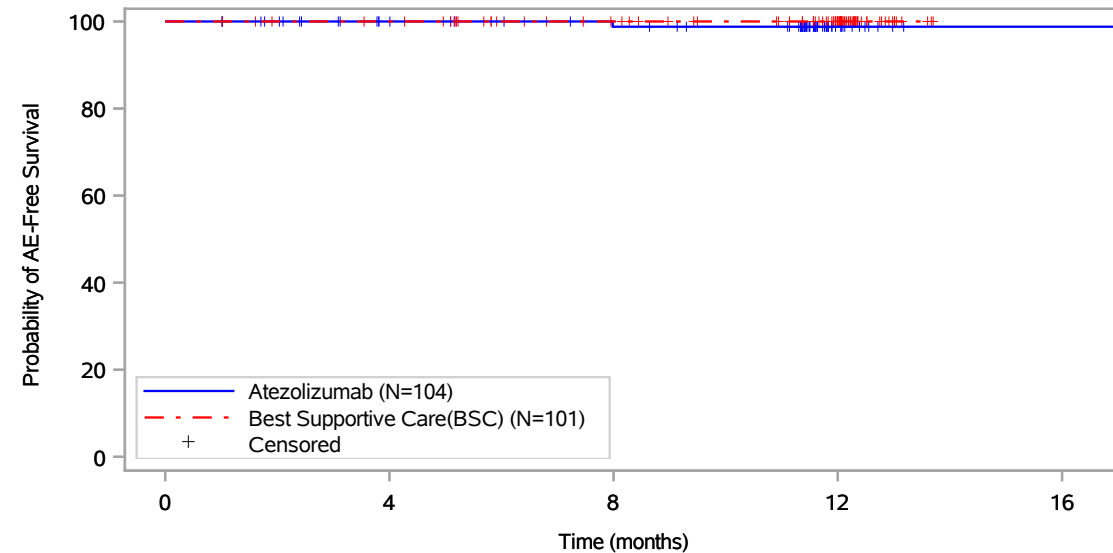
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Vascular disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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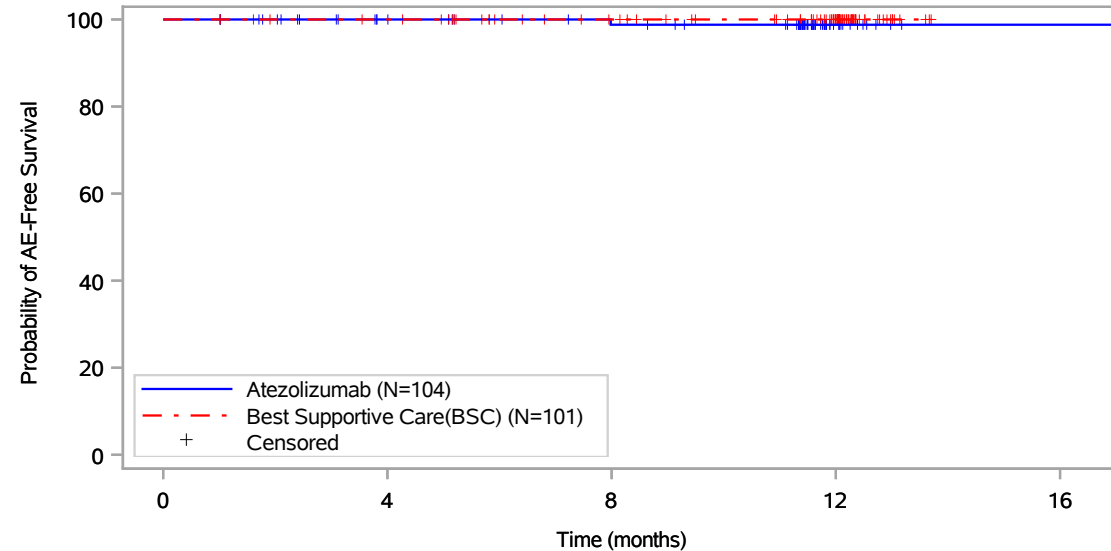
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

Vascular disorders, Hypertension



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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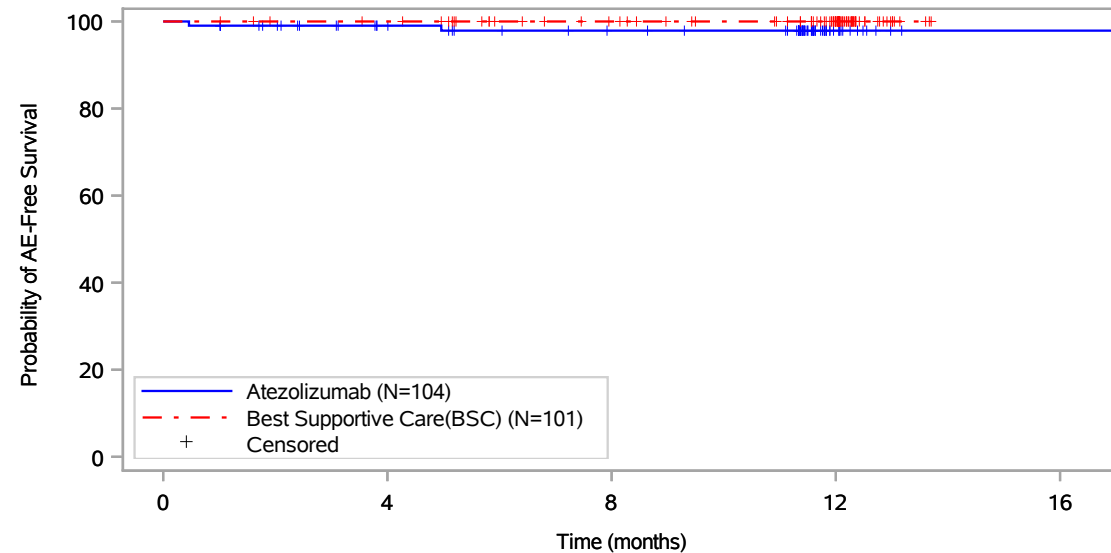
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, All



Patients at risk					
Atezolizumab (N=104)	104	88	80	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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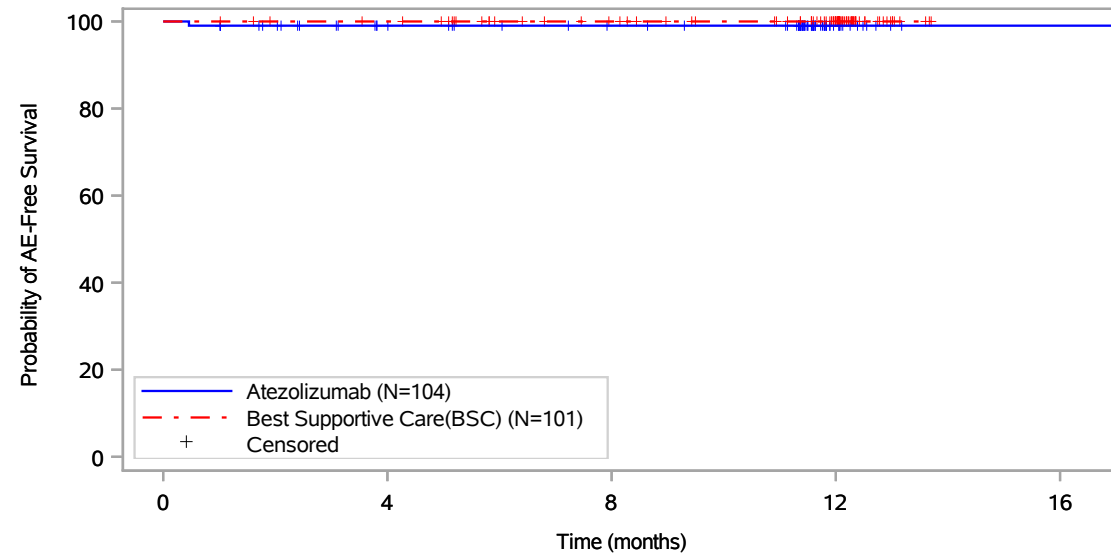
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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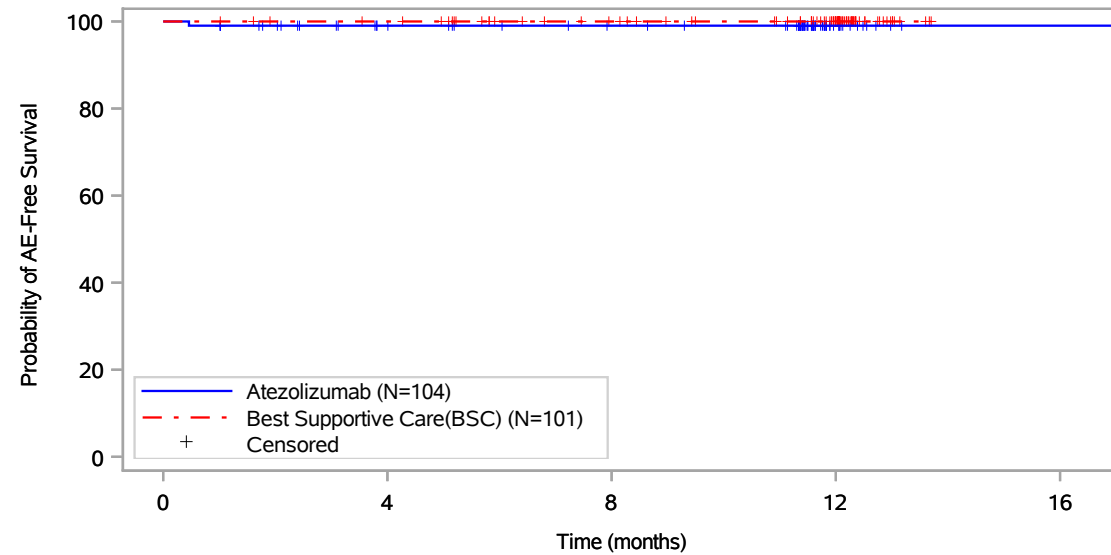
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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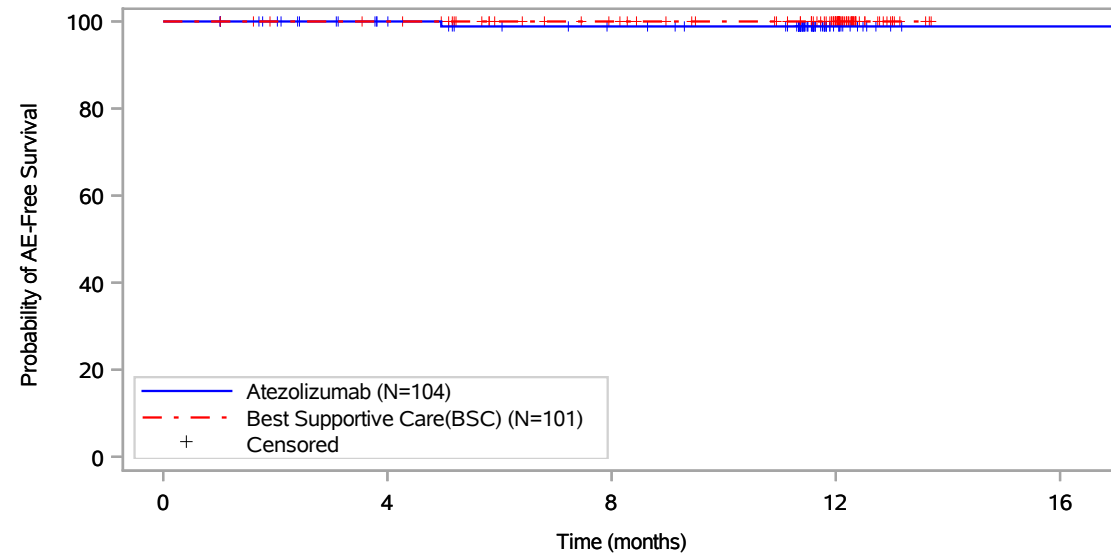
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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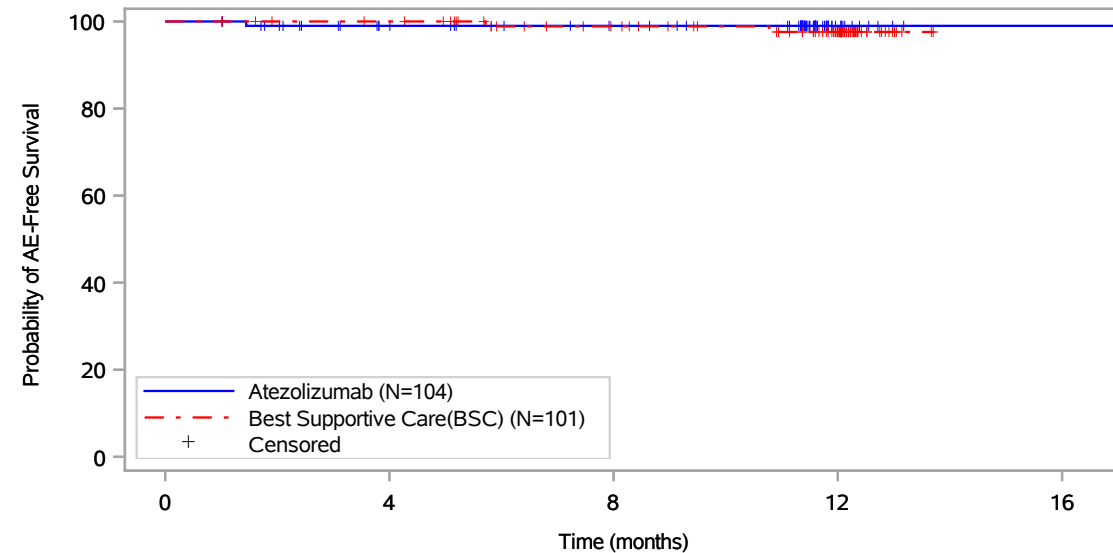
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Eye disorders, All



Patients at risk					
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	82	53	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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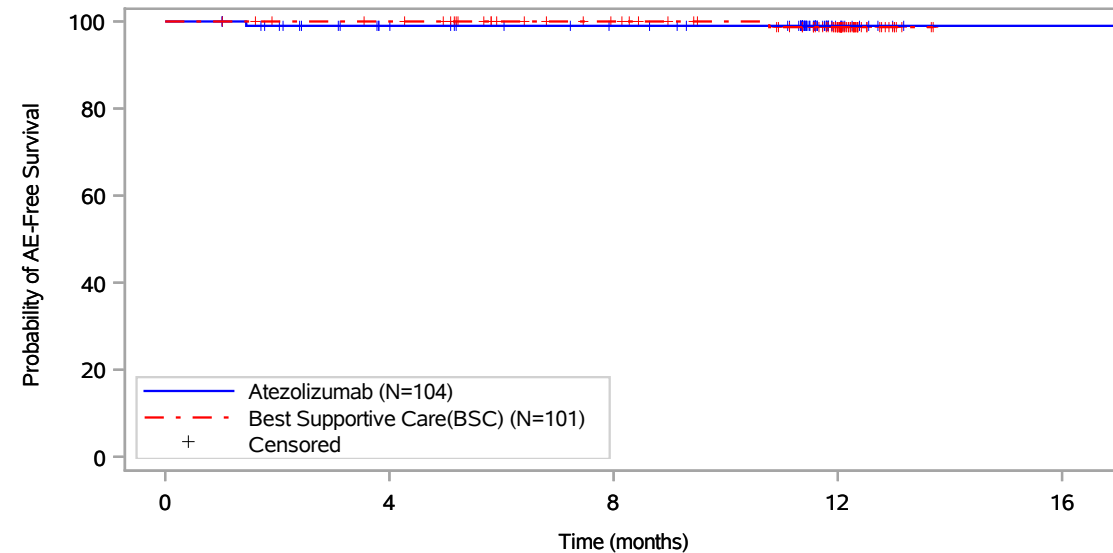
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Eye disorders, Cataract



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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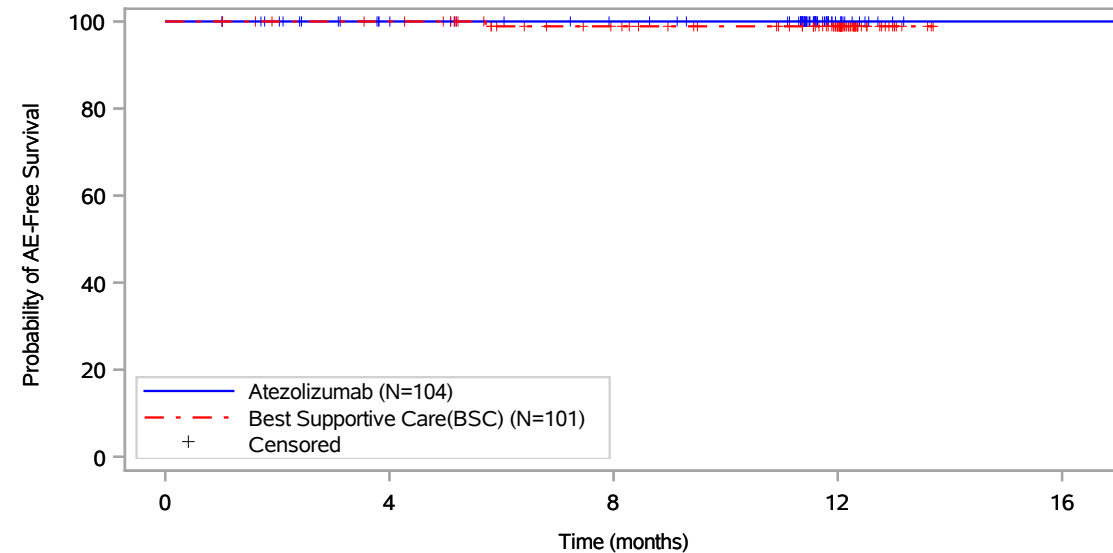
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Eye disorders, Vitreous haemorrhage



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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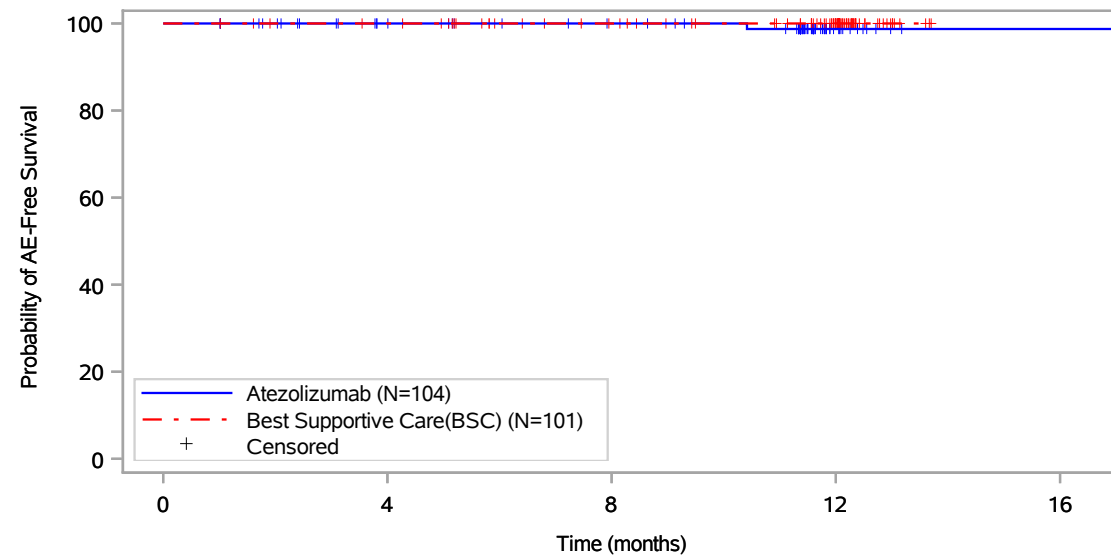
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Gastrointestinal disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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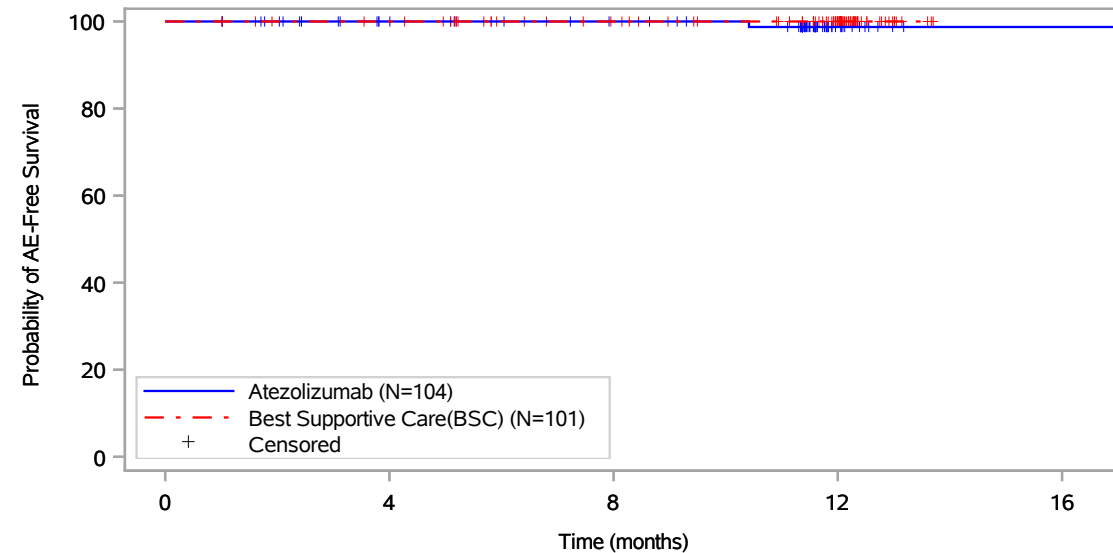
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Colitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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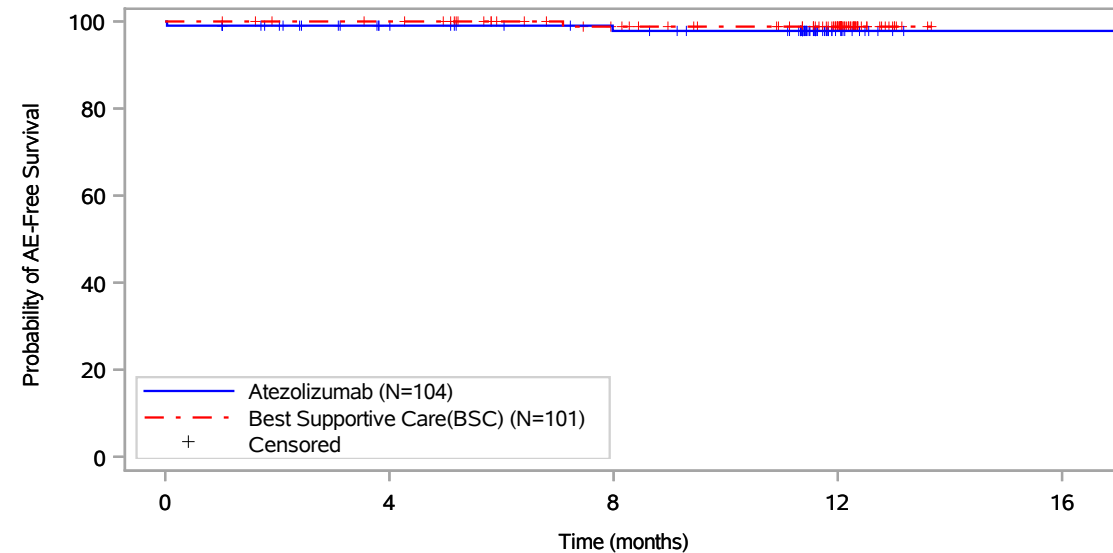
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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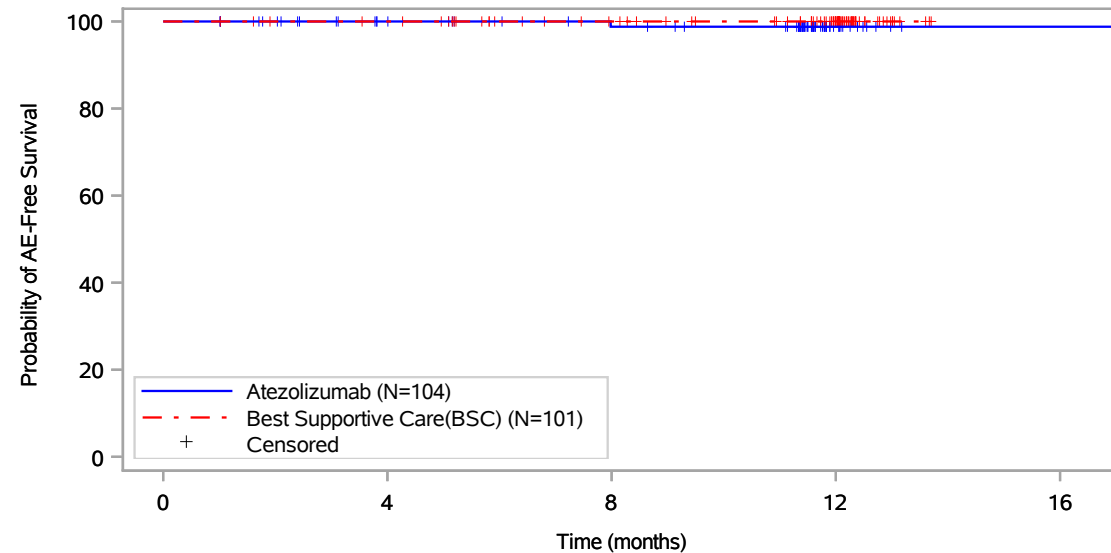
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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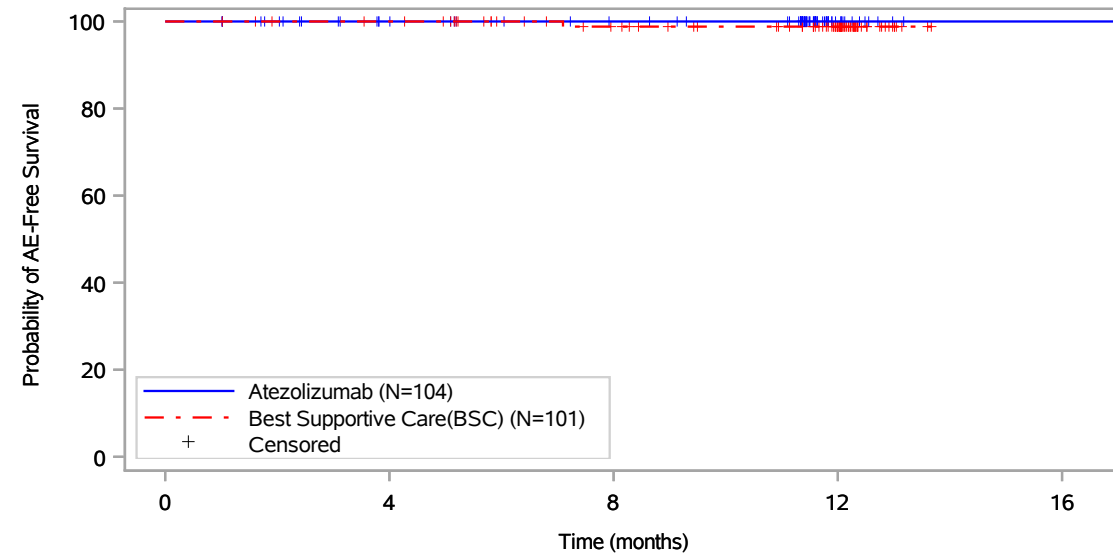
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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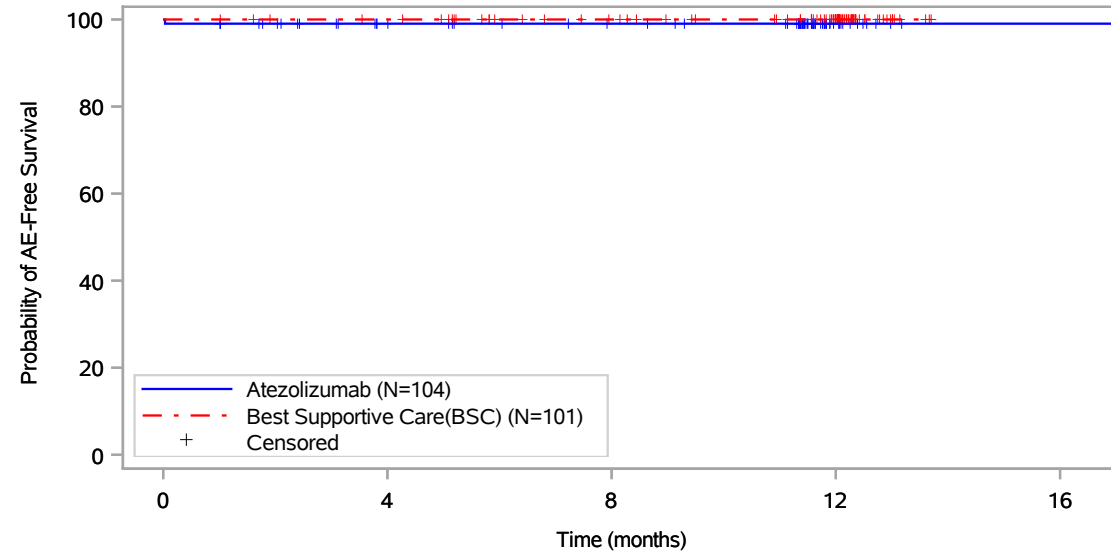
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Pyrexia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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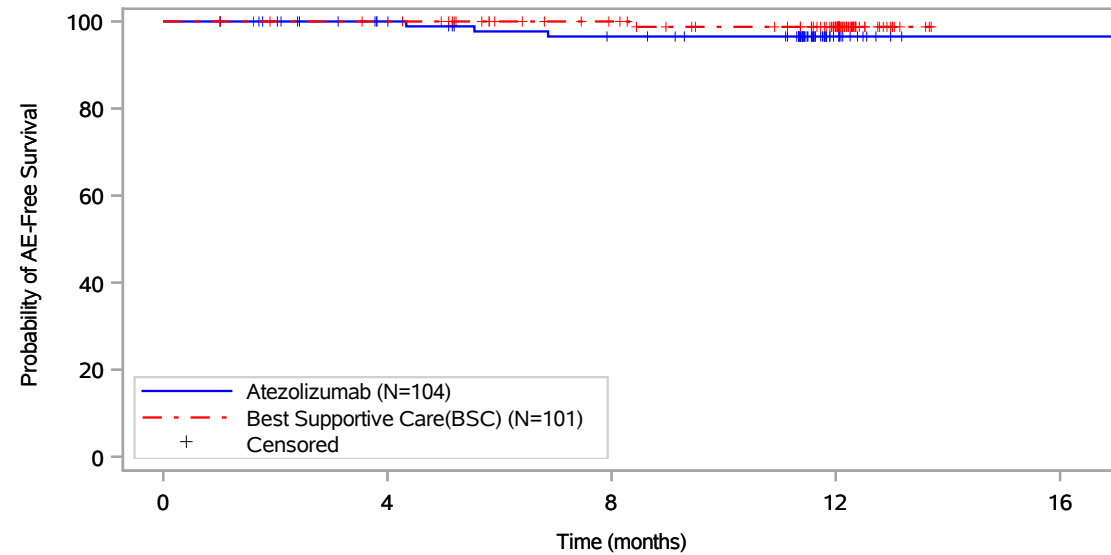
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	19	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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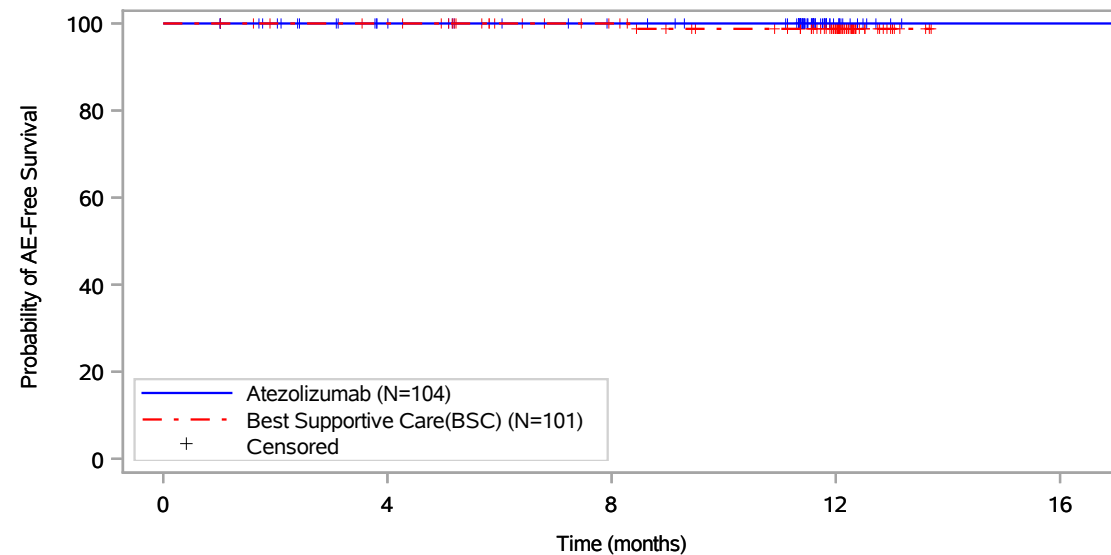
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Cholestasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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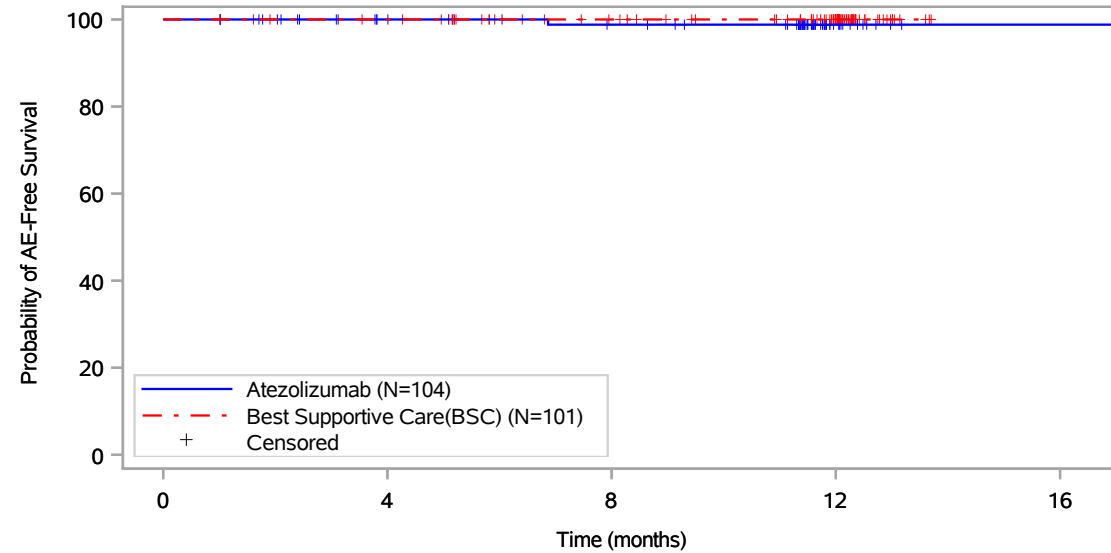
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Drug-induced liver injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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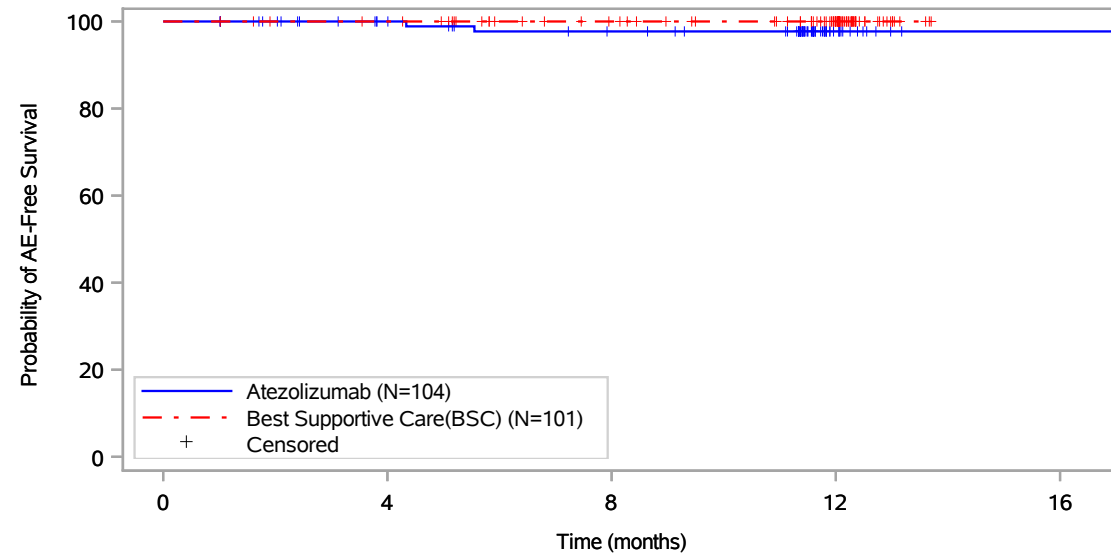
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



Patients at risk					
Atezolizumab (N=104)	104	90	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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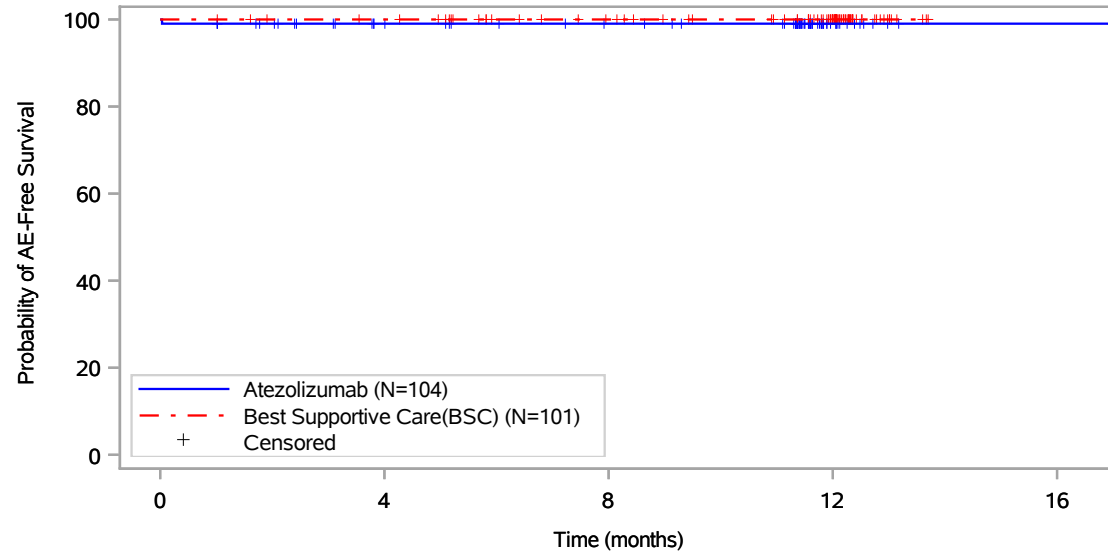
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Immune system disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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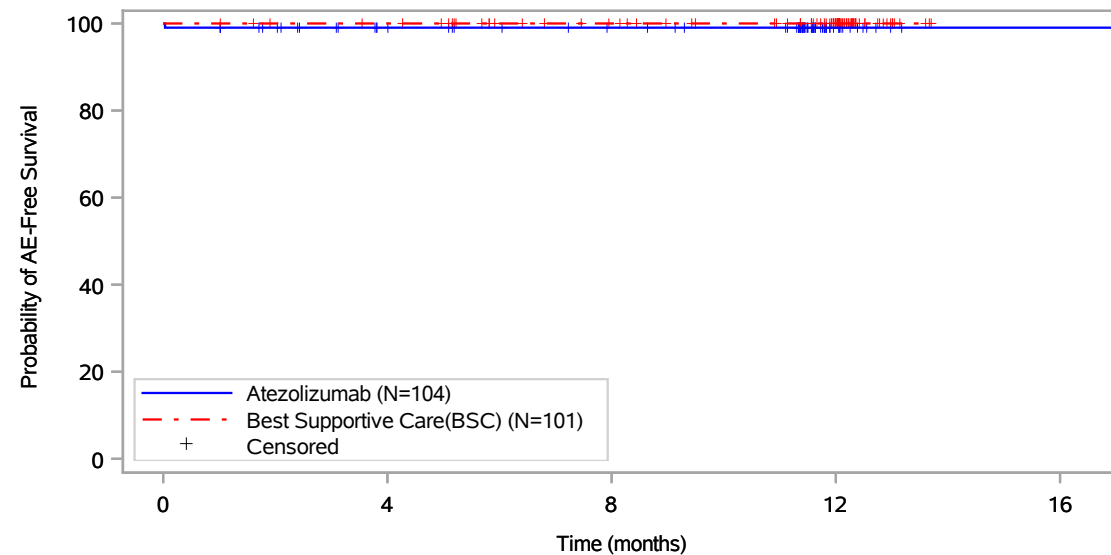
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Immune system disorders, Hypersensitivity



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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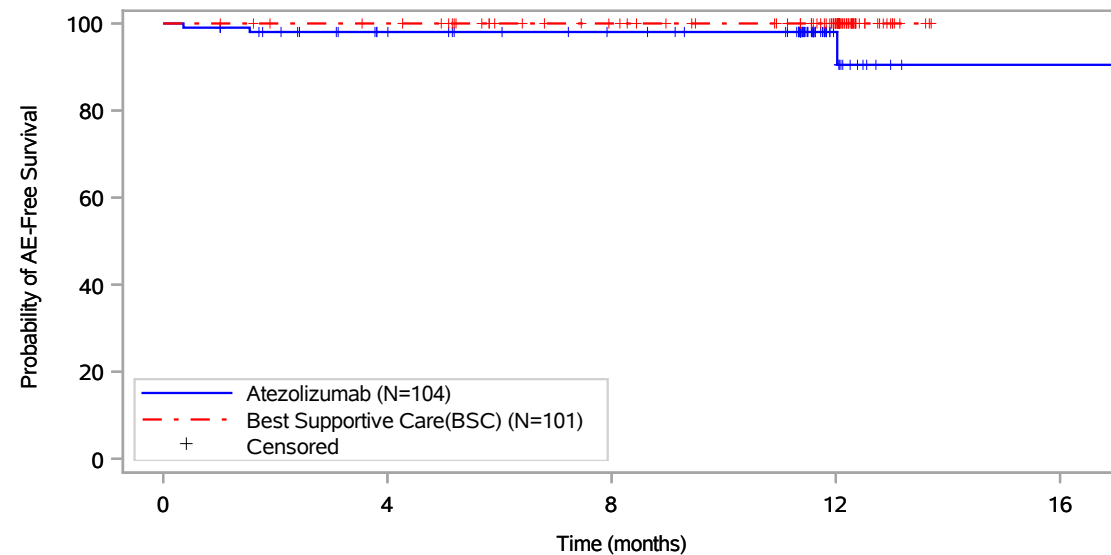
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Infections and infestations, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	13	20	89	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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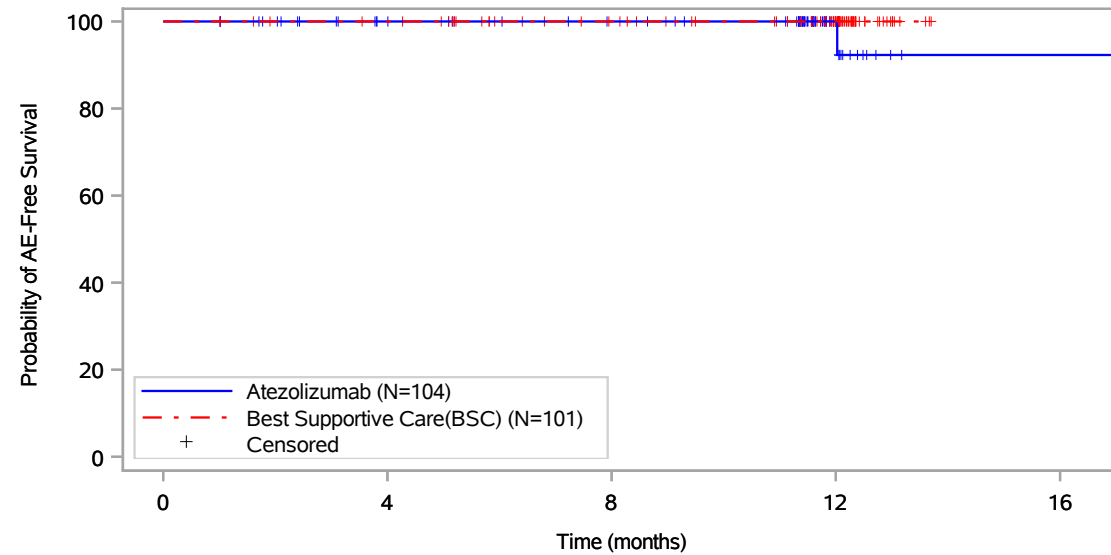
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Infections and infestations, Cellulitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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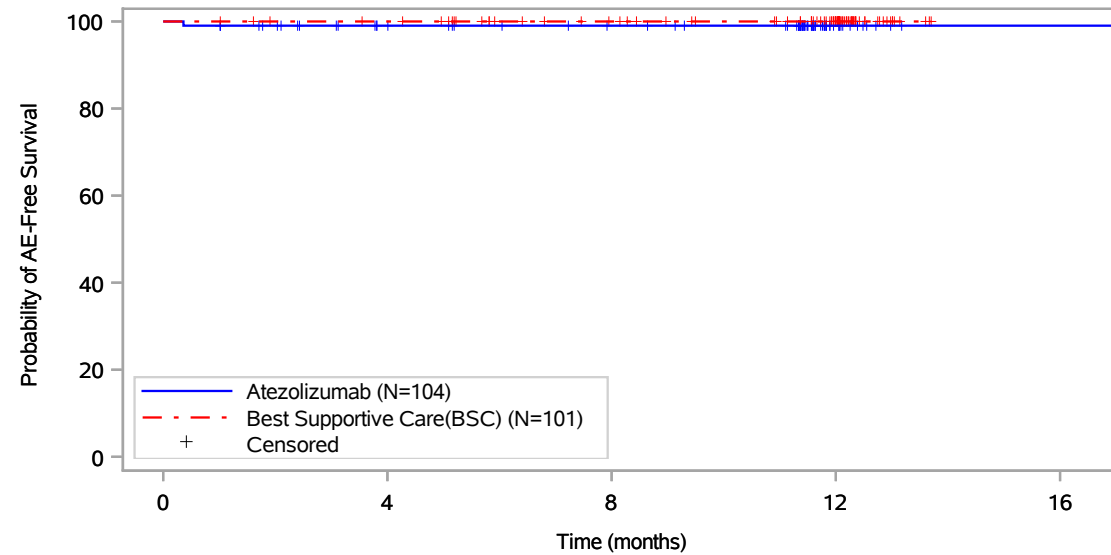
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Infections and infestations, Encephalitis



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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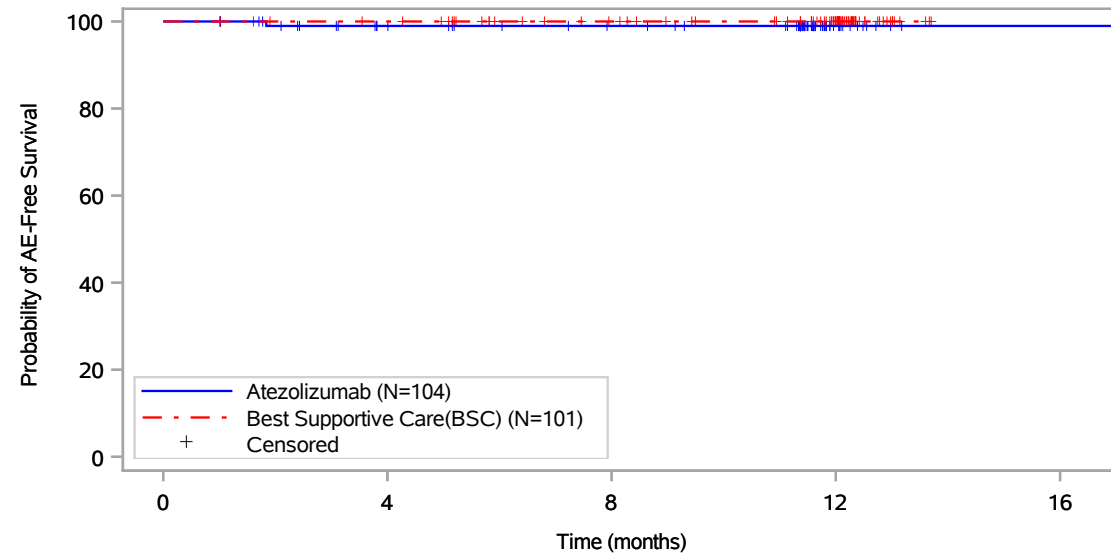
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Infections and infestations, Kidney infection



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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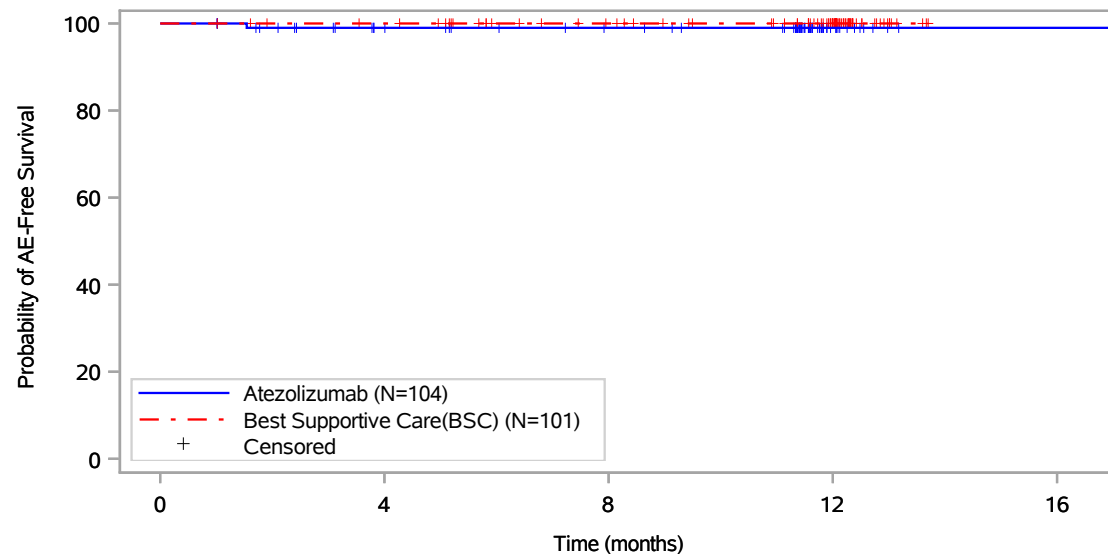
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Infections and infestations, Meningitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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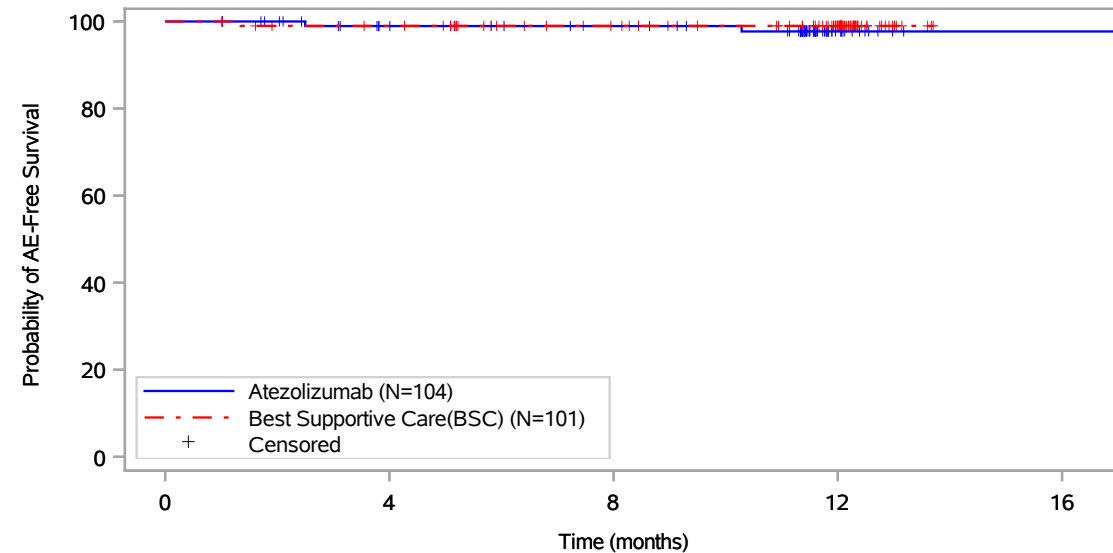
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Investigations, All



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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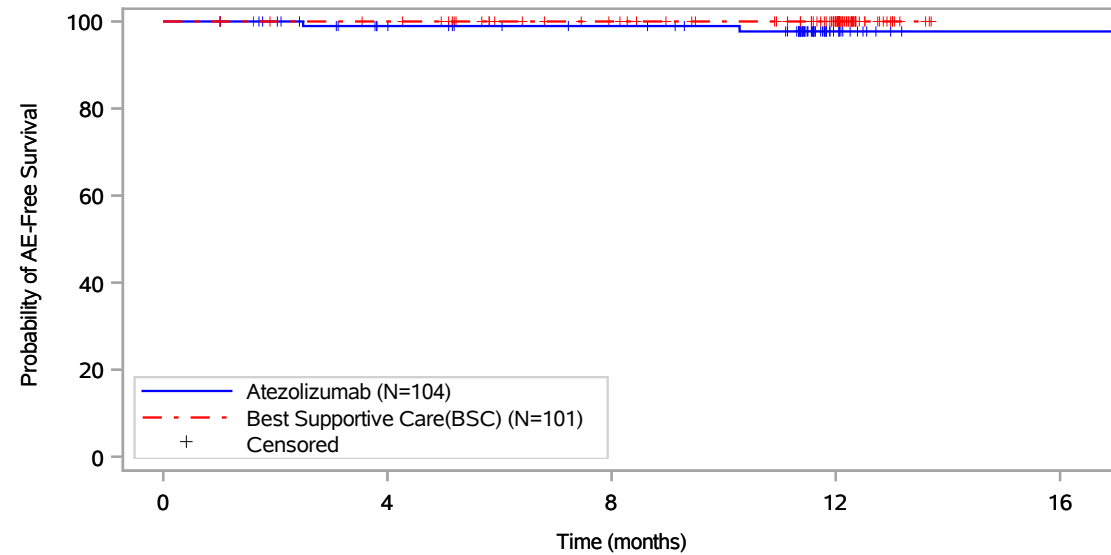
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk					
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	20	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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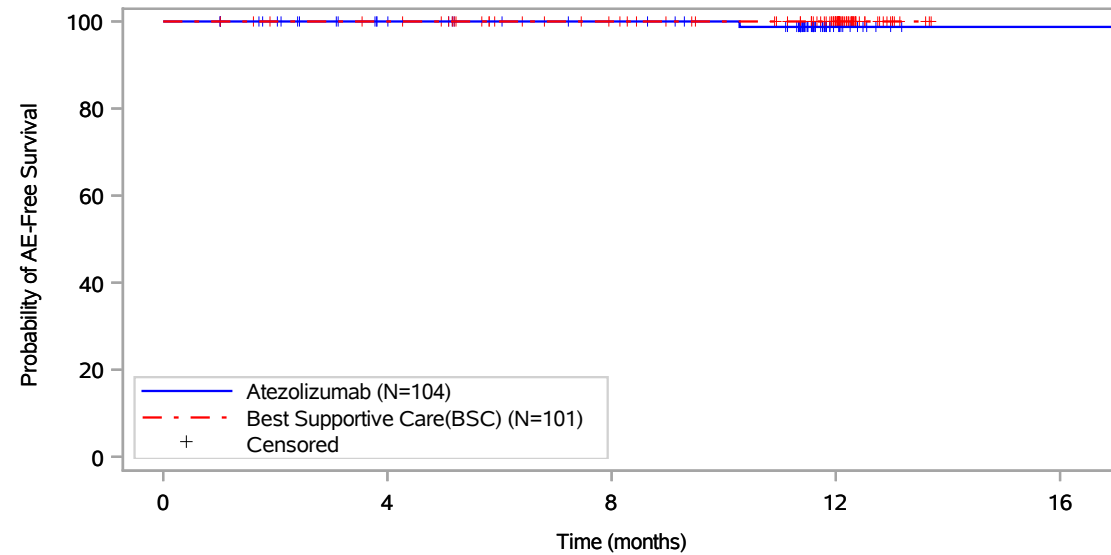
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	83	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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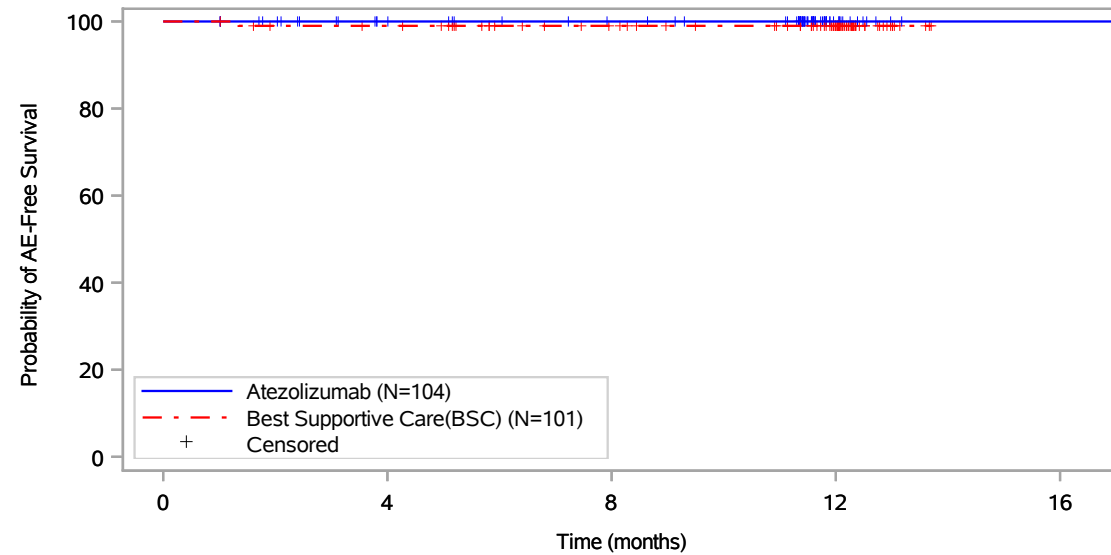
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Investigations, Neutrophil count decreased



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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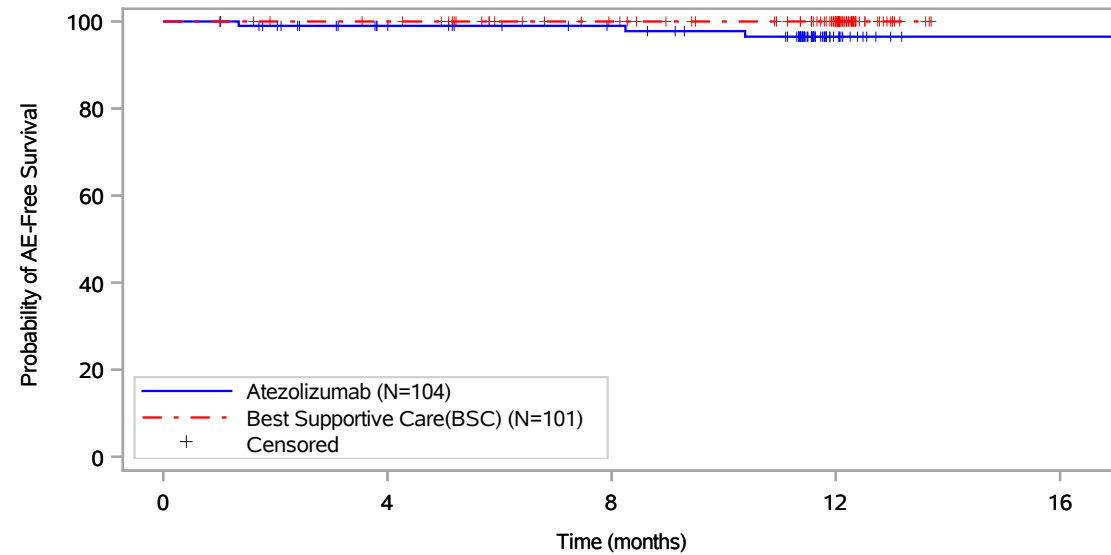
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	88	100
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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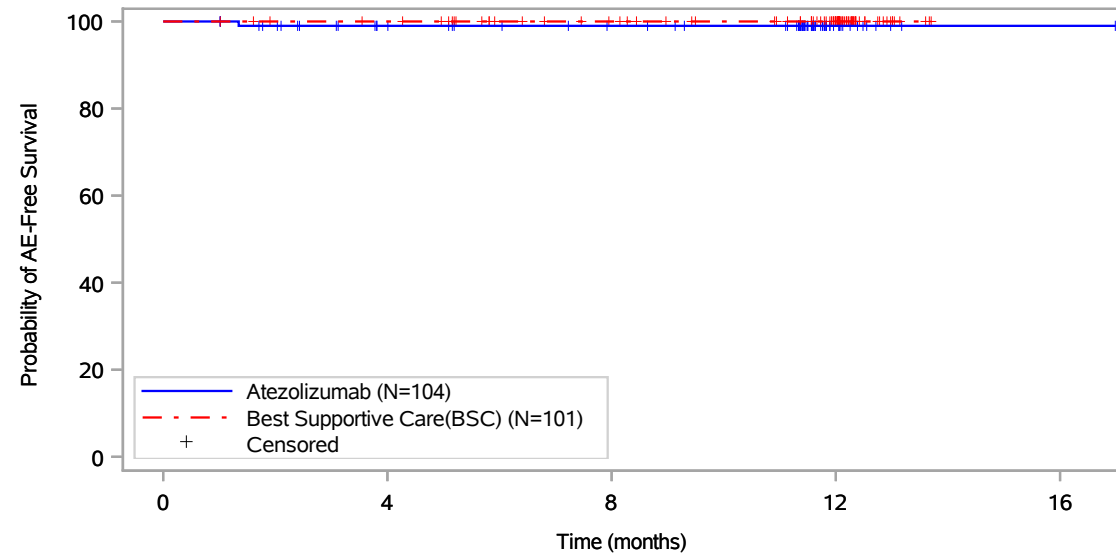
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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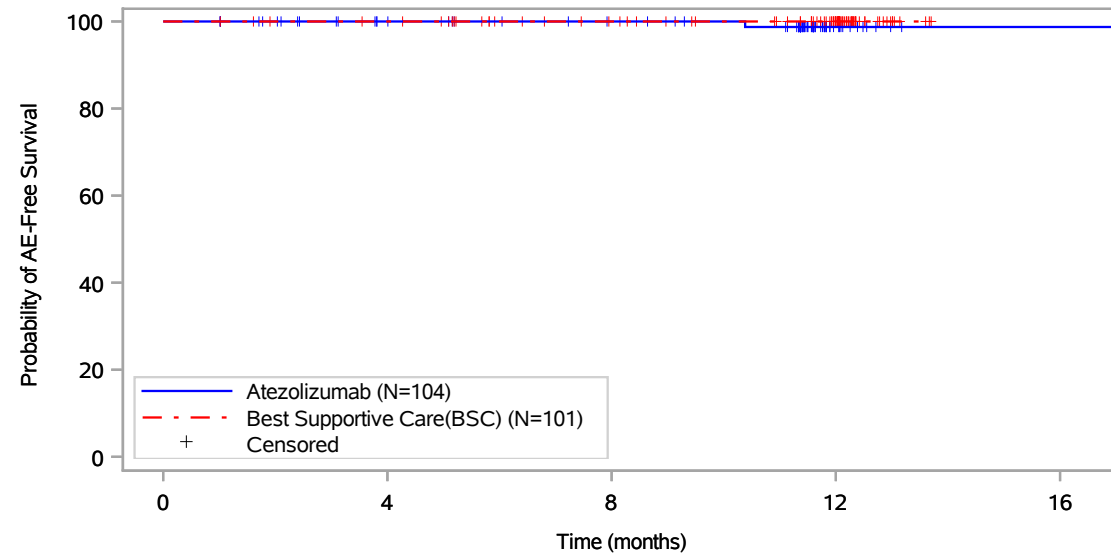
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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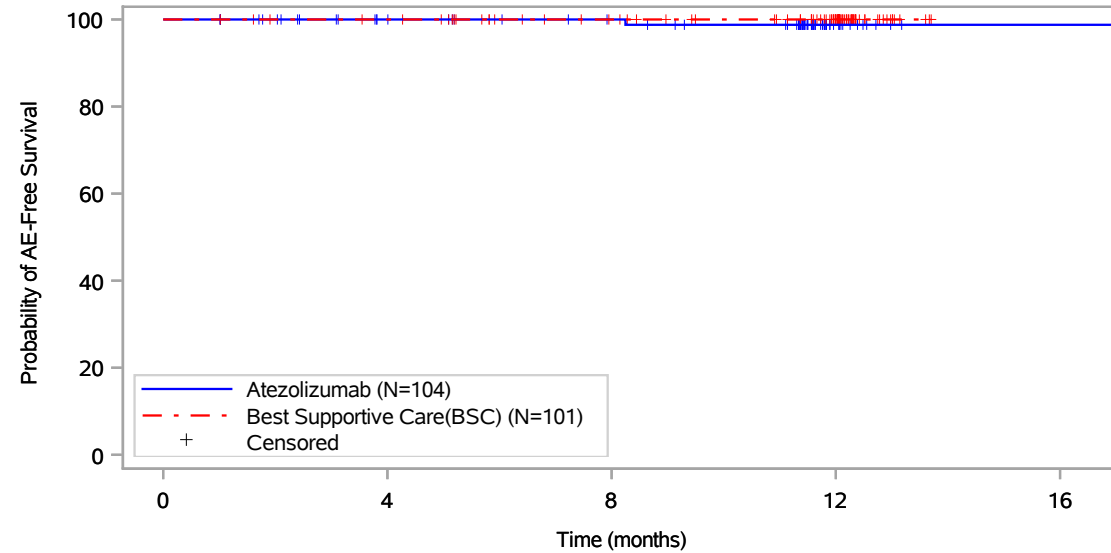
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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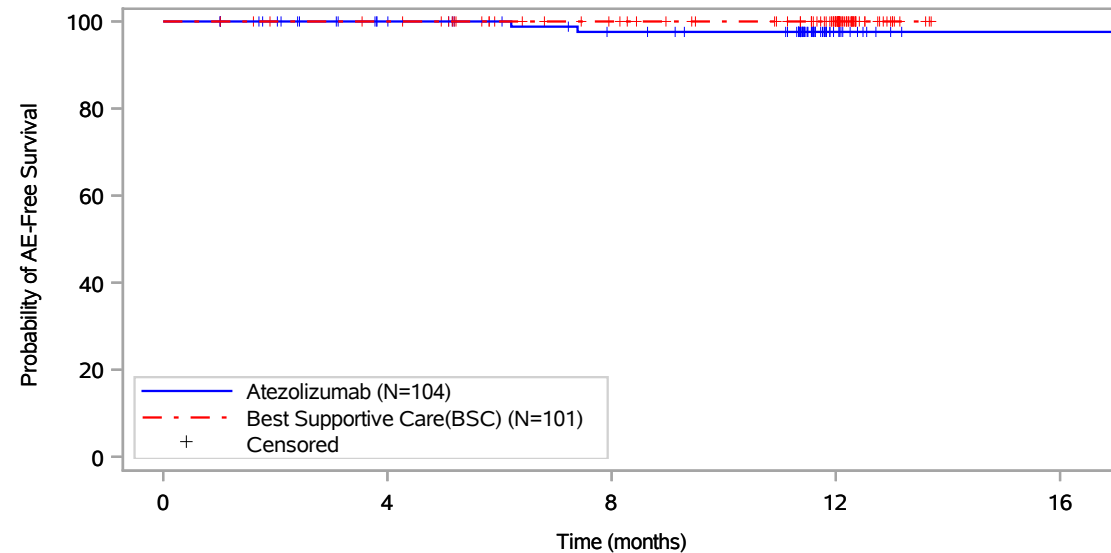
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	80	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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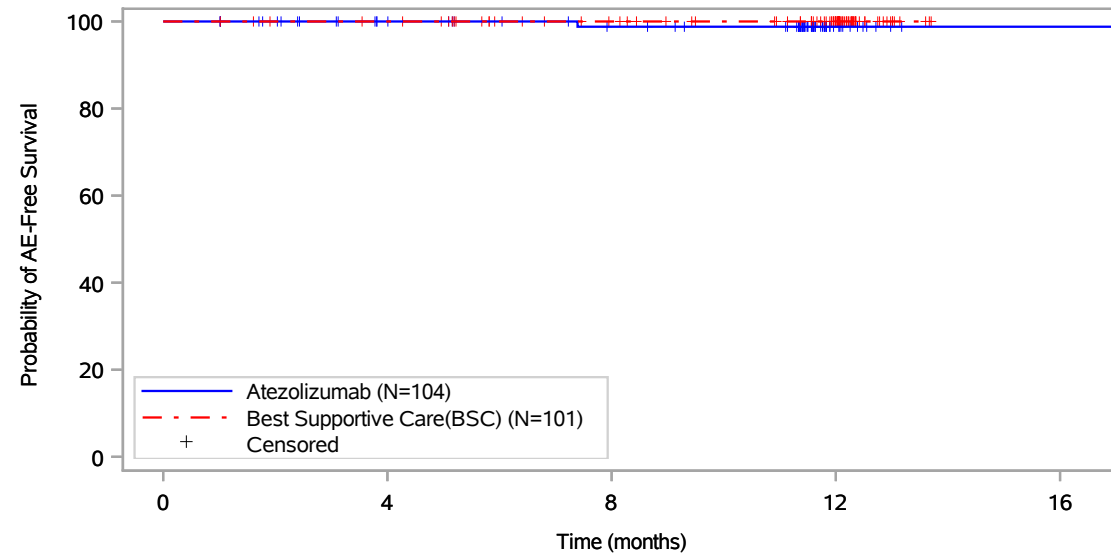
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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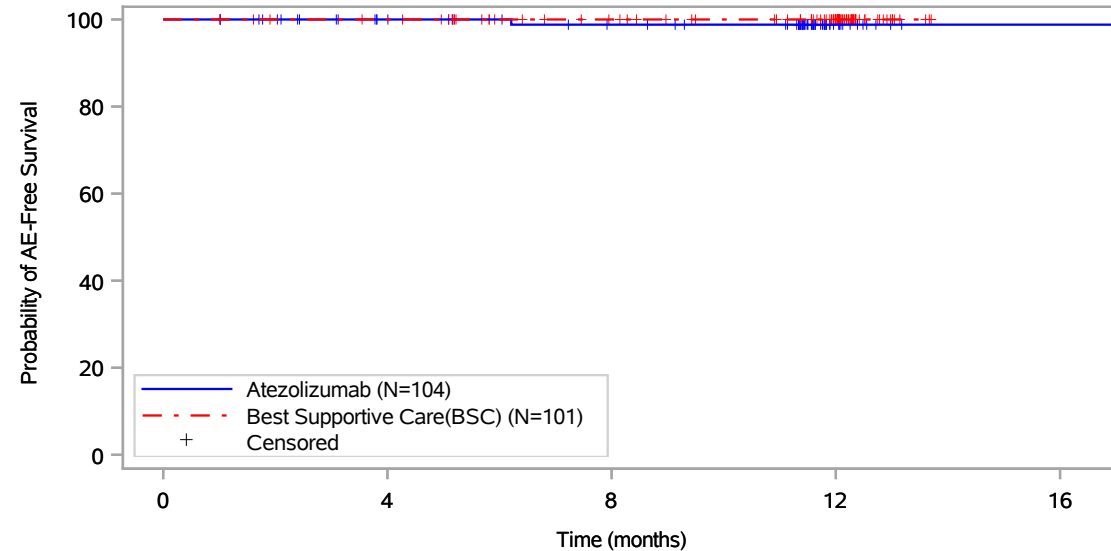
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..DFS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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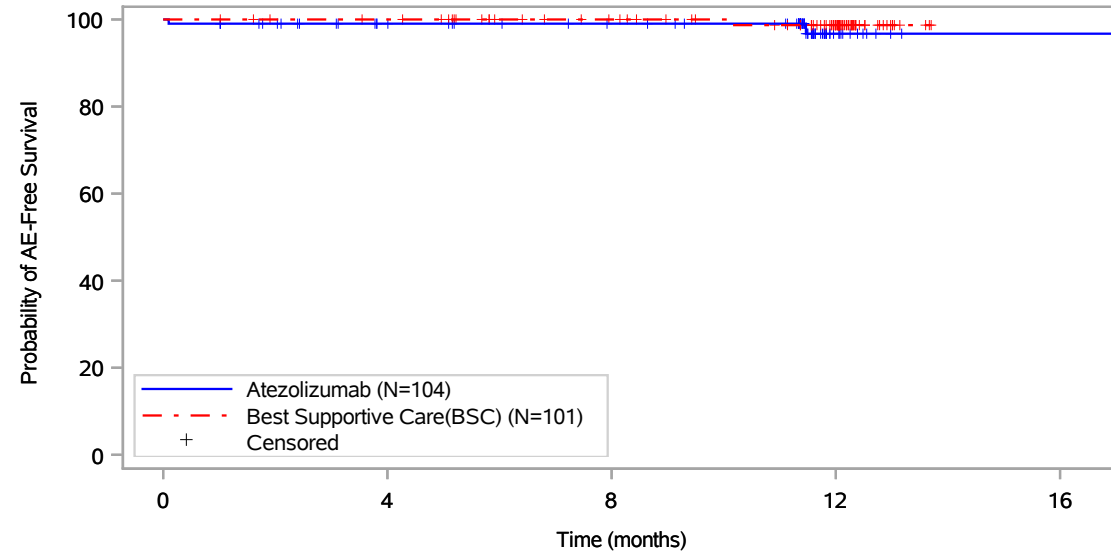
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk					
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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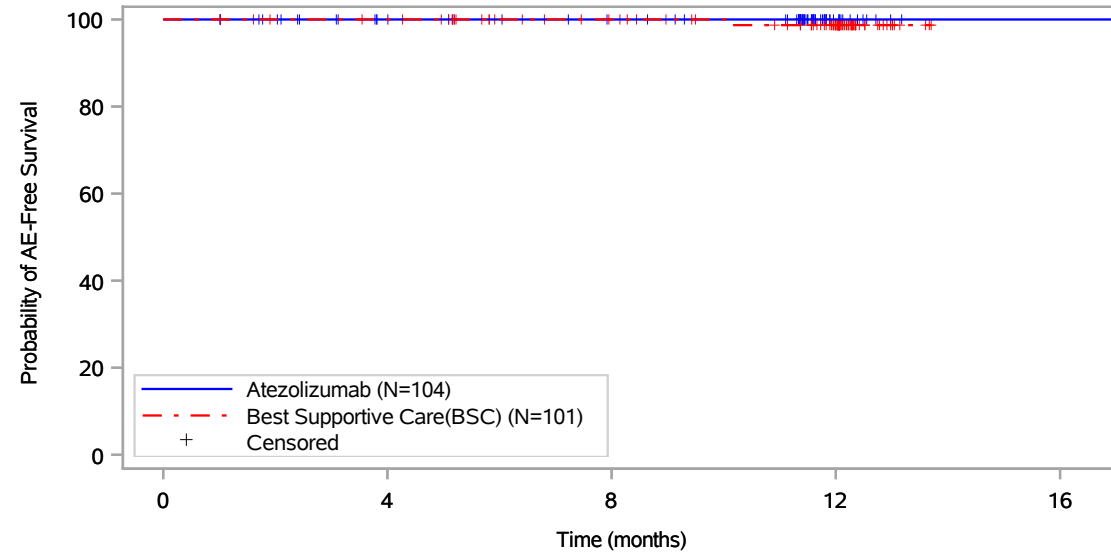
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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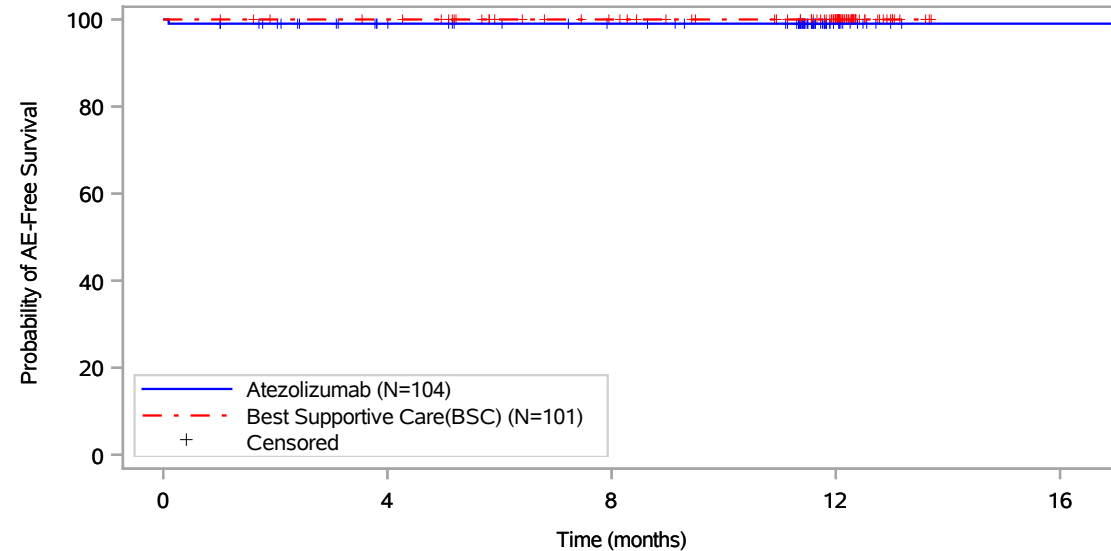
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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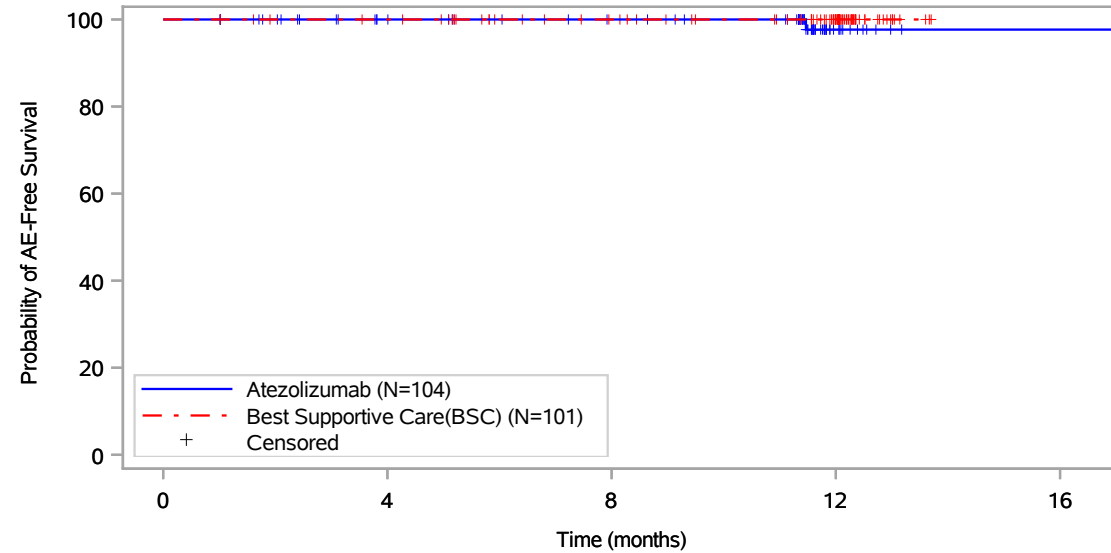
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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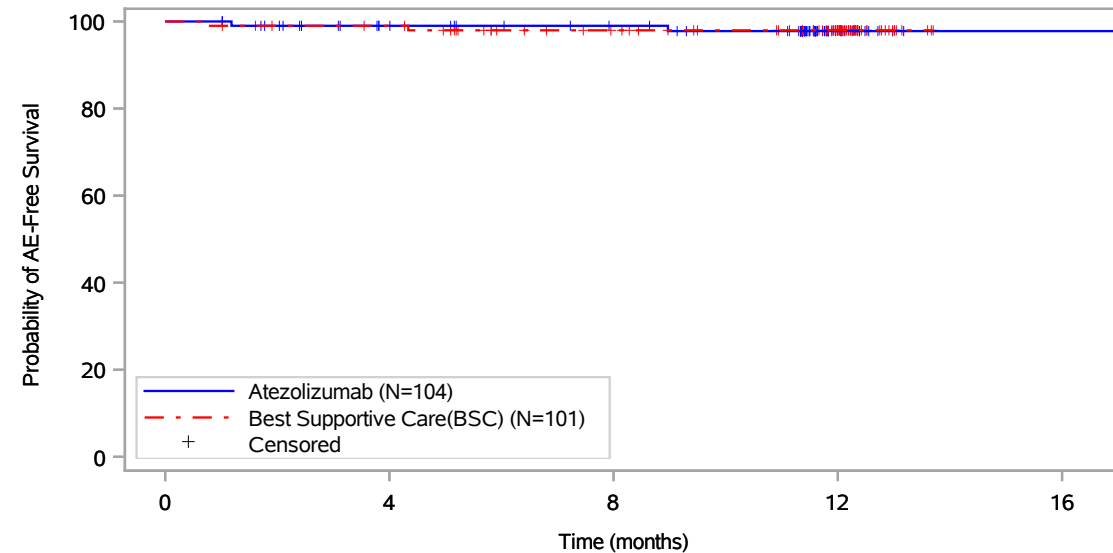
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	81	54	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	89	101
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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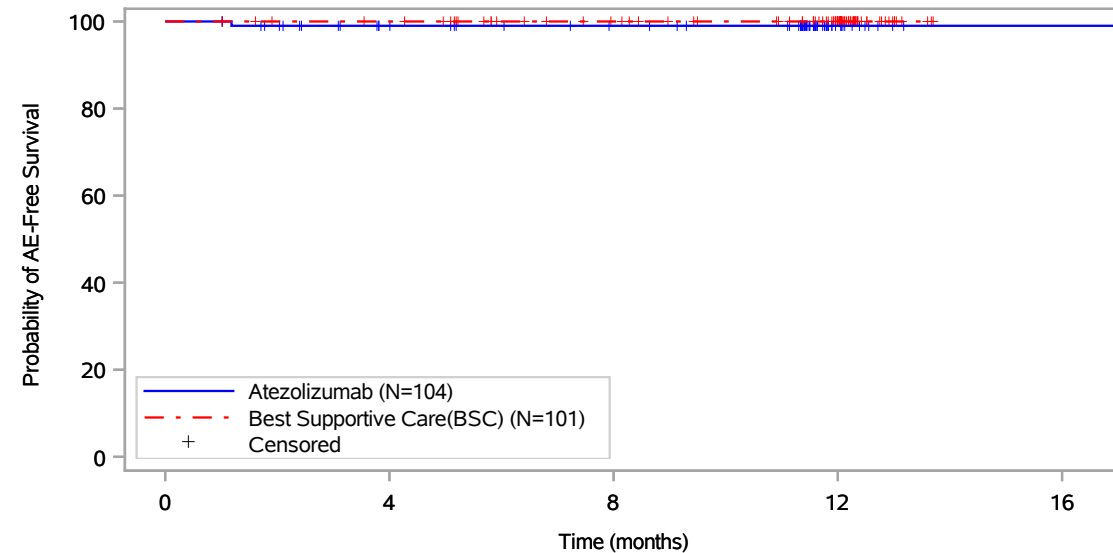
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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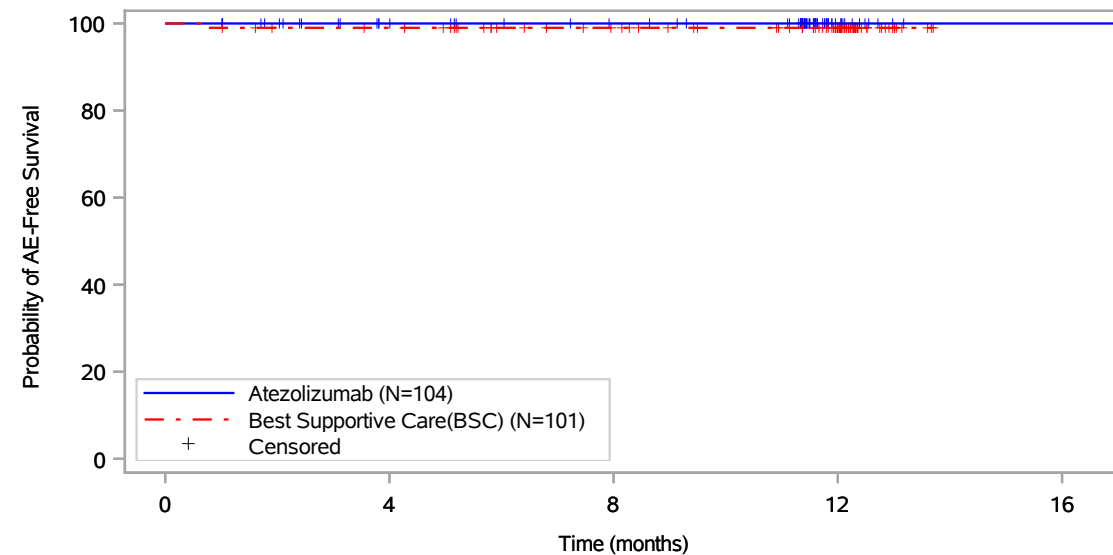
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, Paraesthesia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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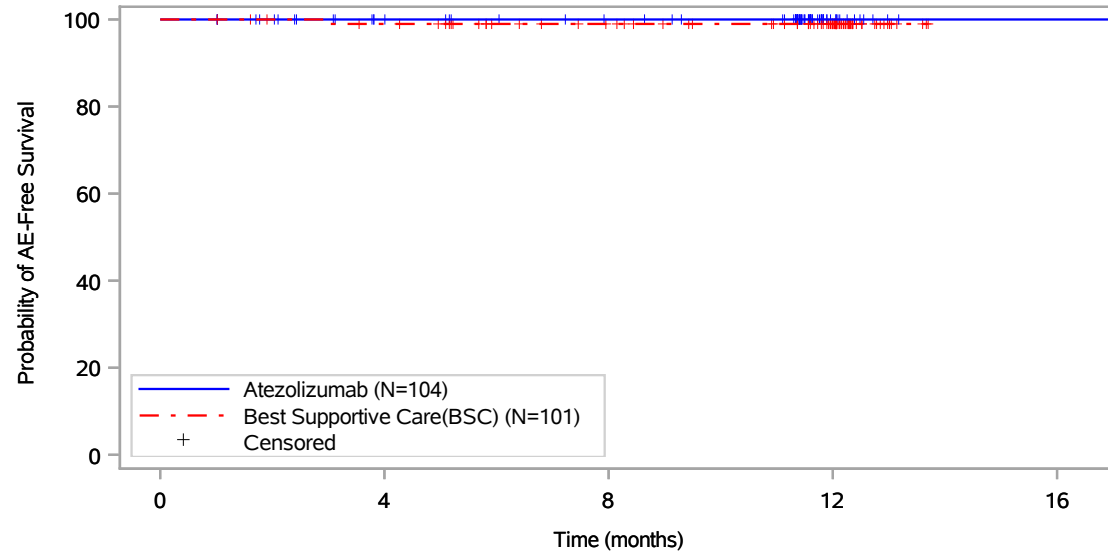
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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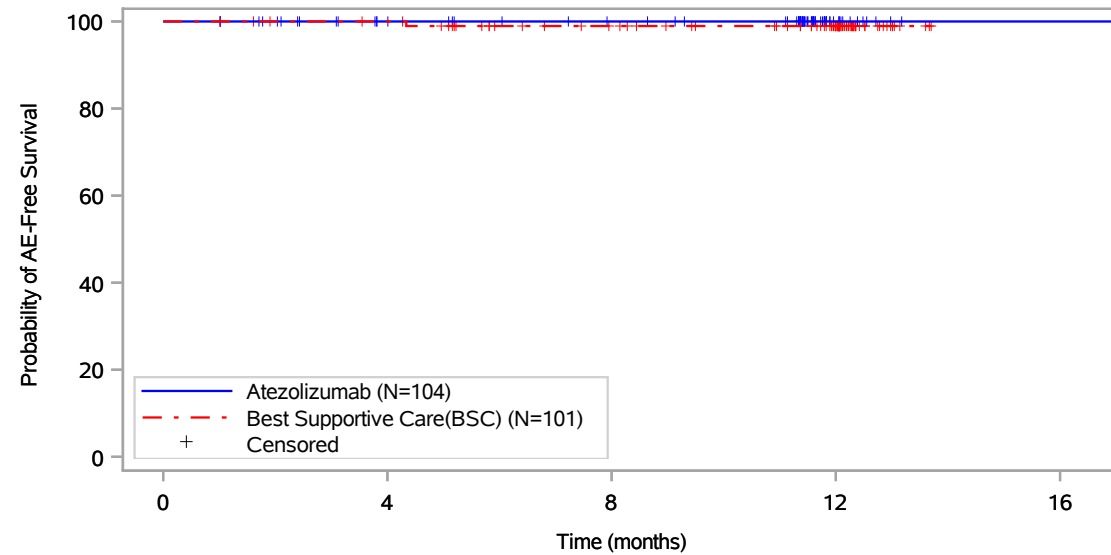
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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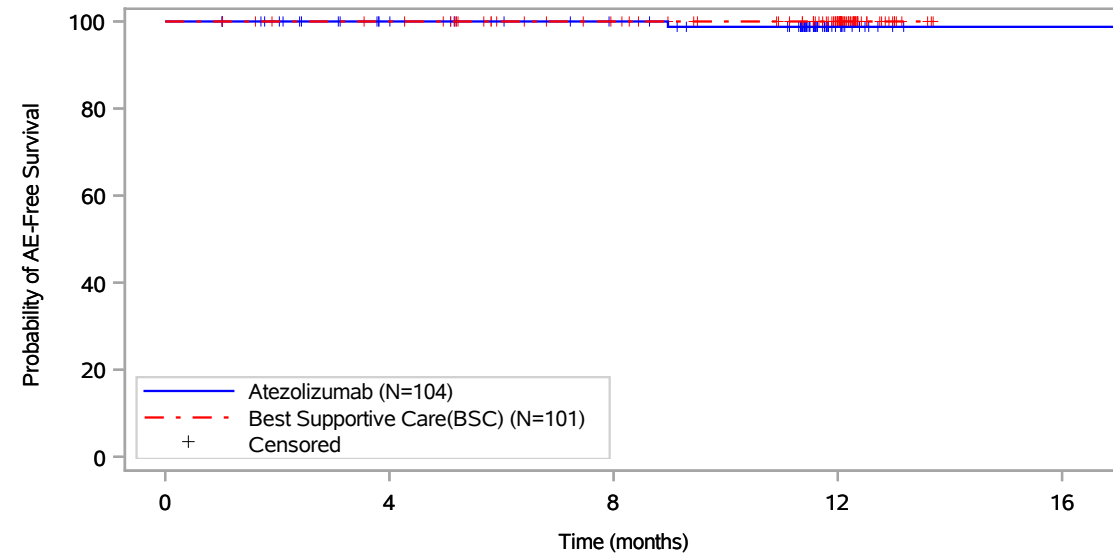
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Nervous system disorders, Syncope



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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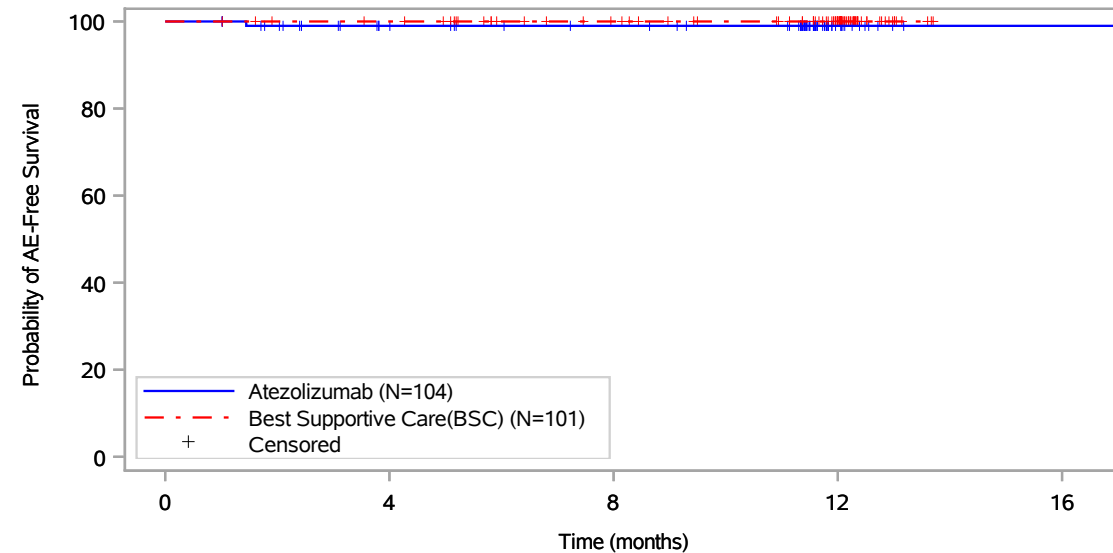
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Renal and urinary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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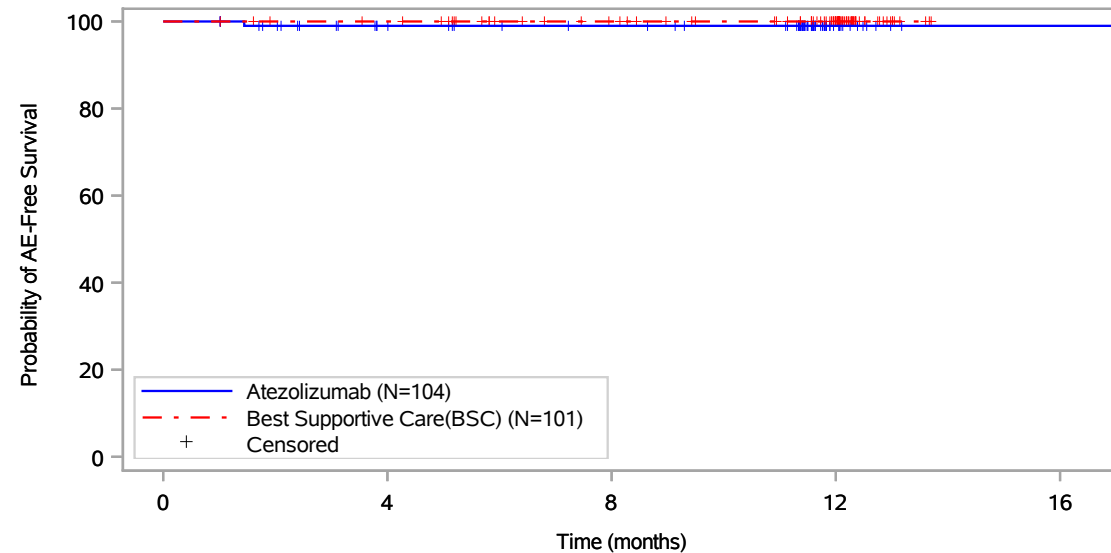
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



Patients at risk					
Atezolizumab (N=104)	104	88	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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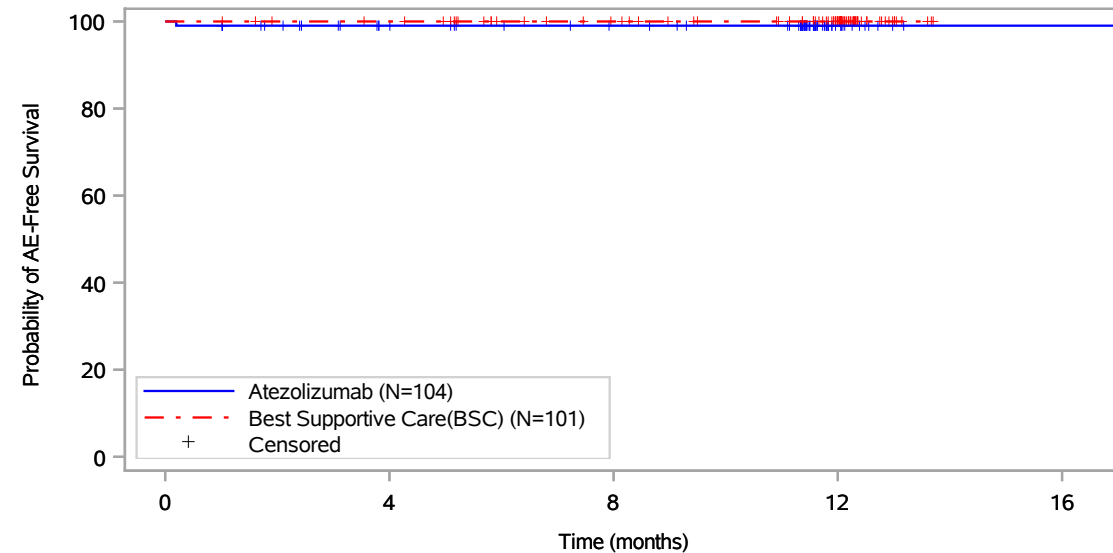
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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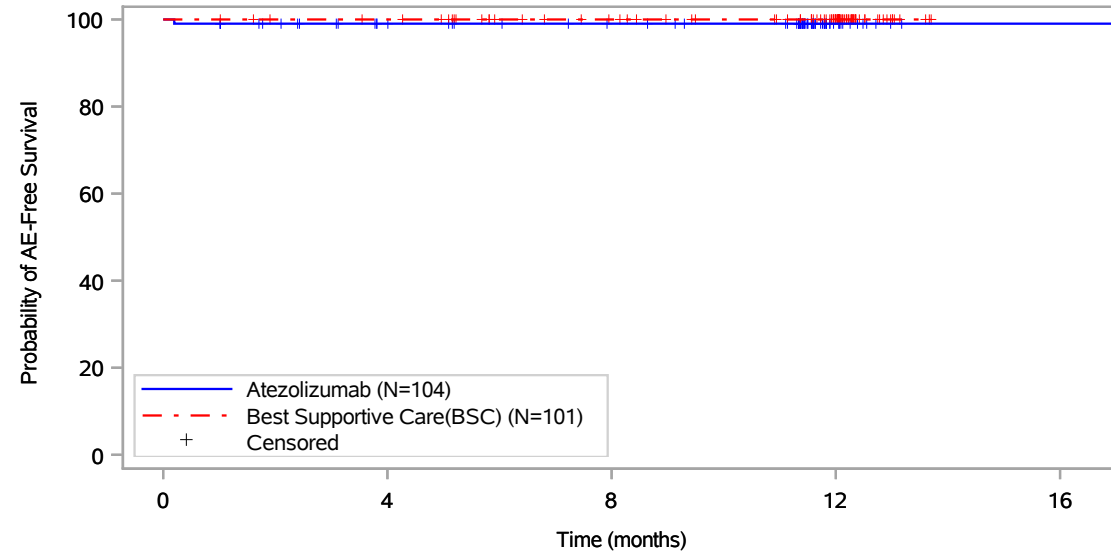
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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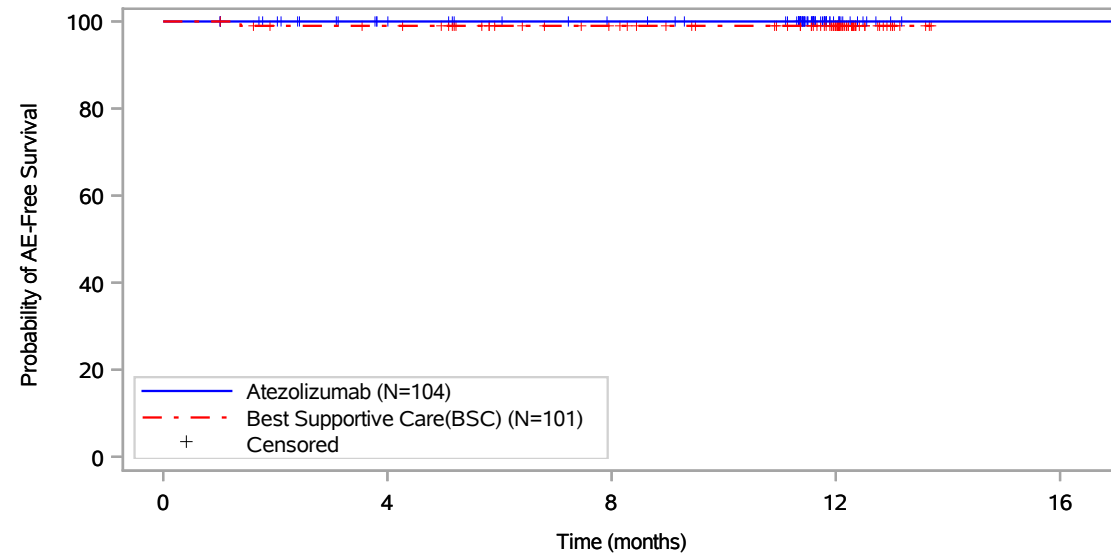
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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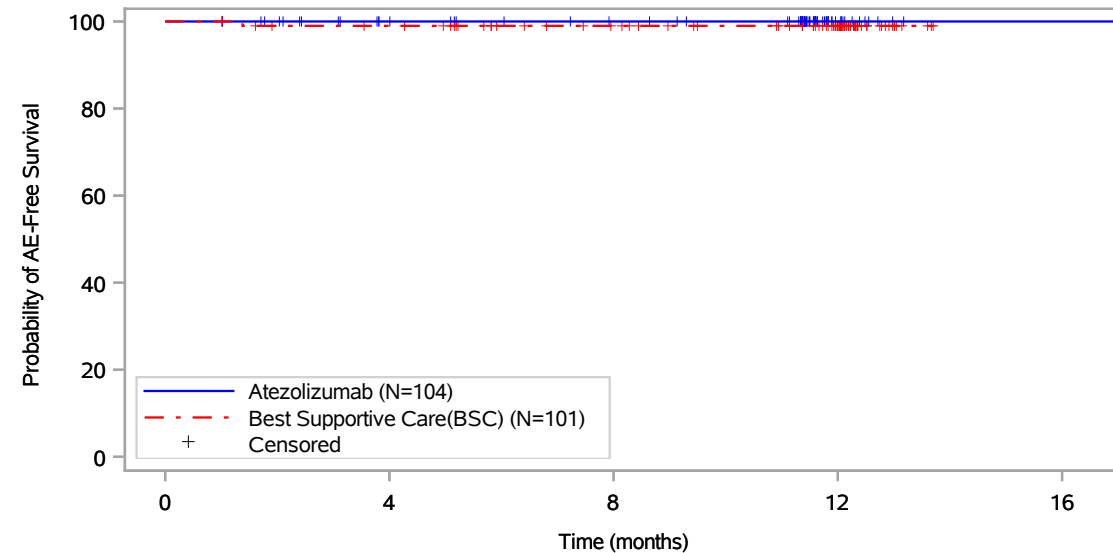
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	96	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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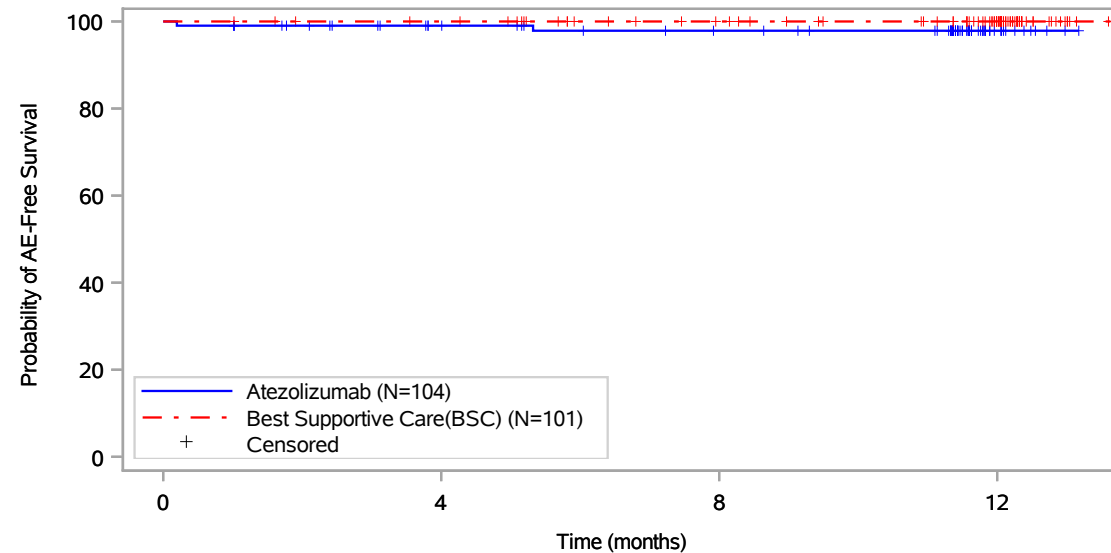
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	89	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	14	21	90
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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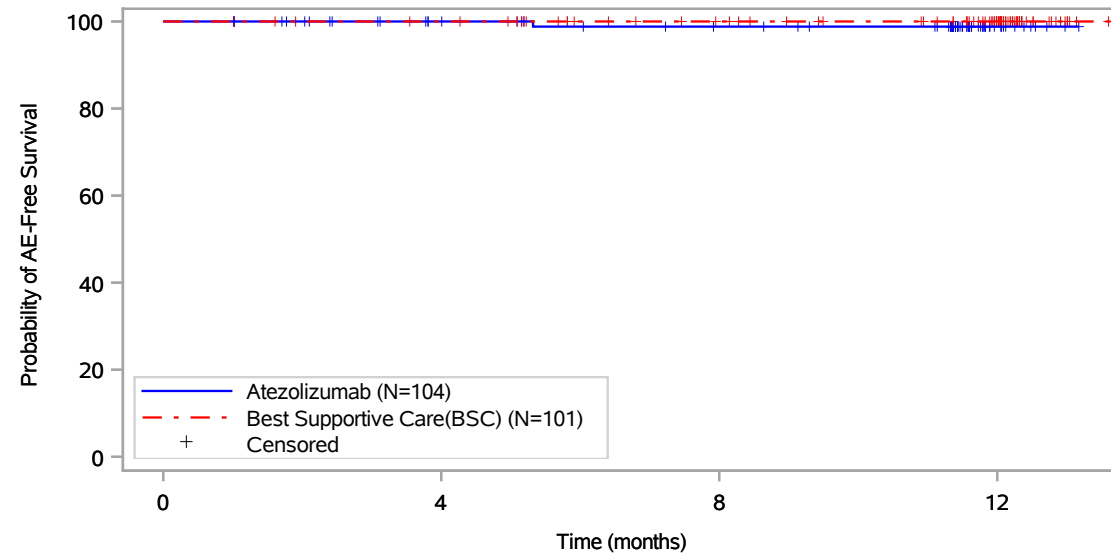
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	89	81	12
Best Supportive Care(BSC) (N=101)	101	97	83	55
Patients censored				
Atezolizumab (N=104)	0	15	22	91
Best Supportive Care(BSC) (N=101)	0	4	18	46

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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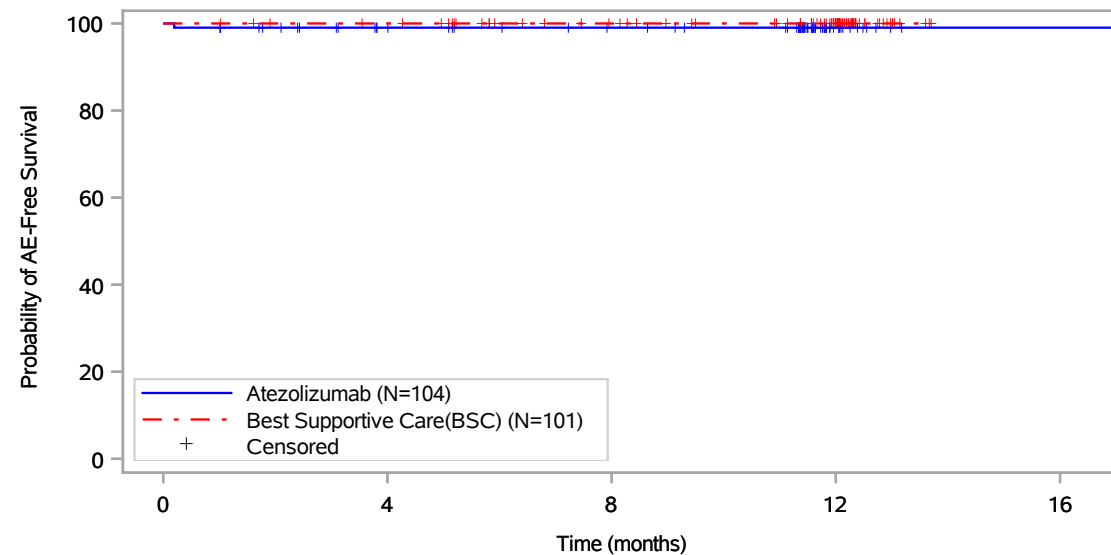
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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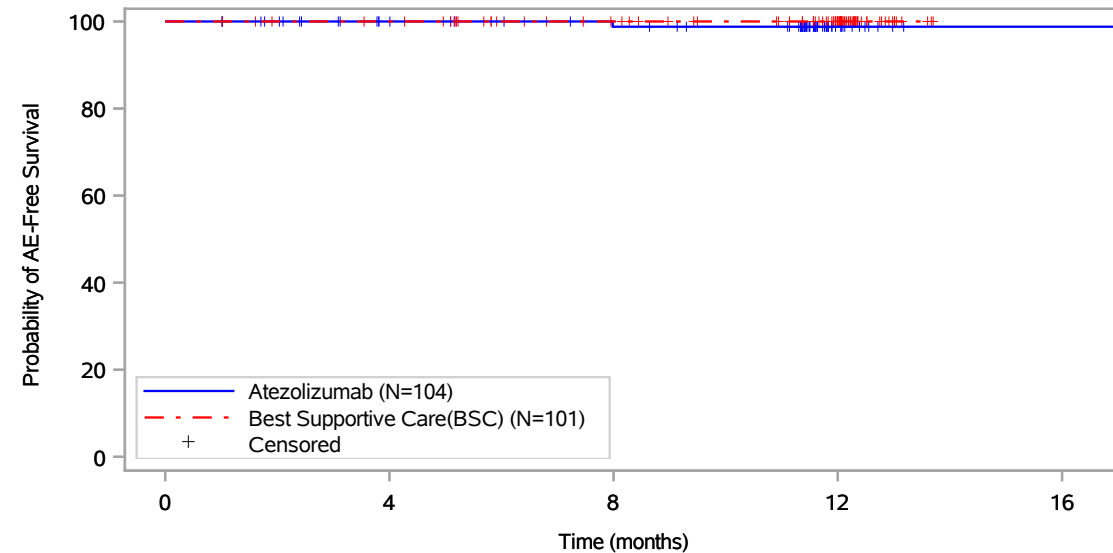
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Vascular disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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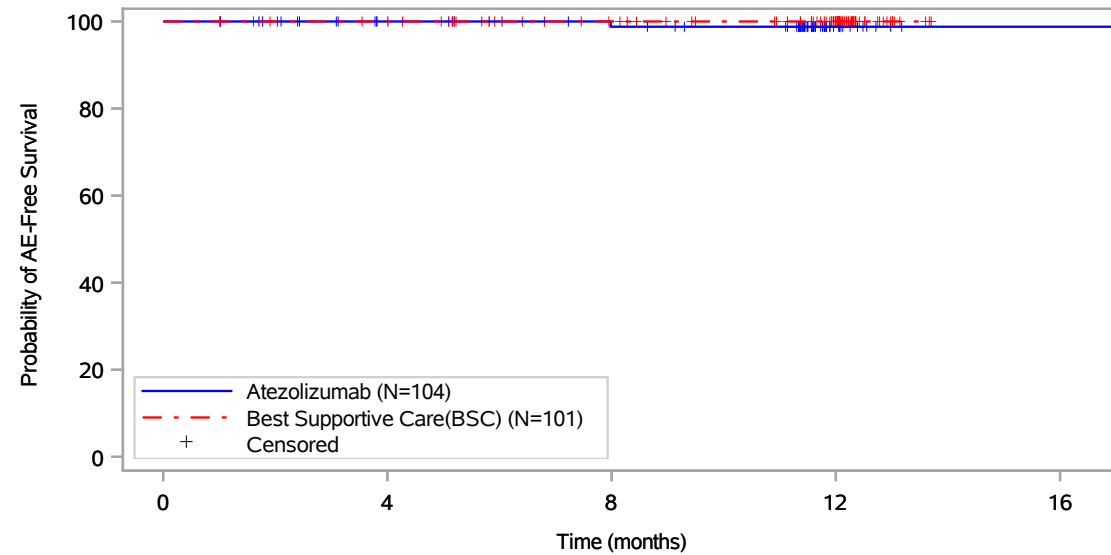
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3 Adverse Event

STUDY: GO29527

Vascular disorders, Hypertension



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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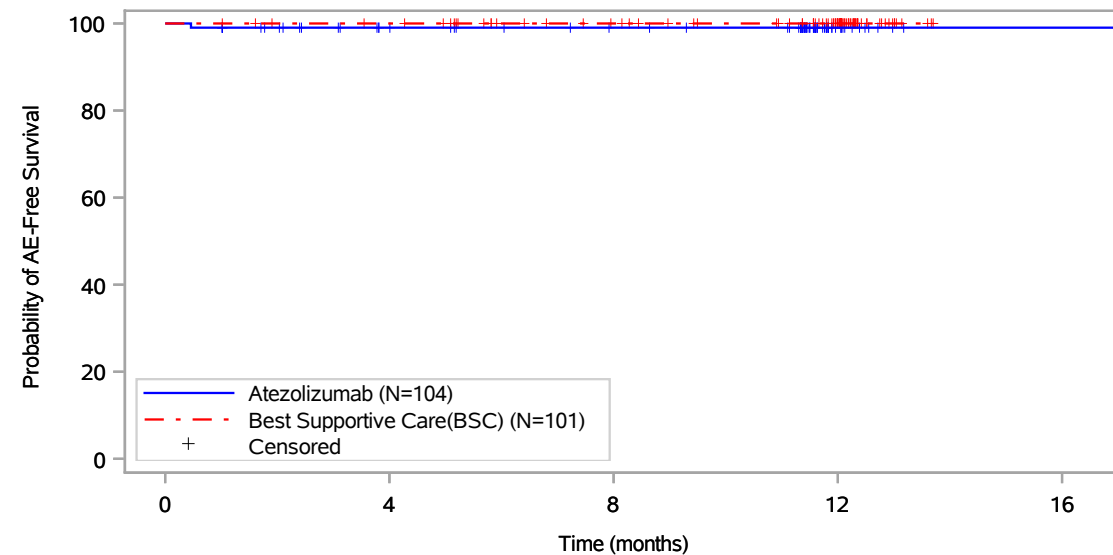
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Endocrine disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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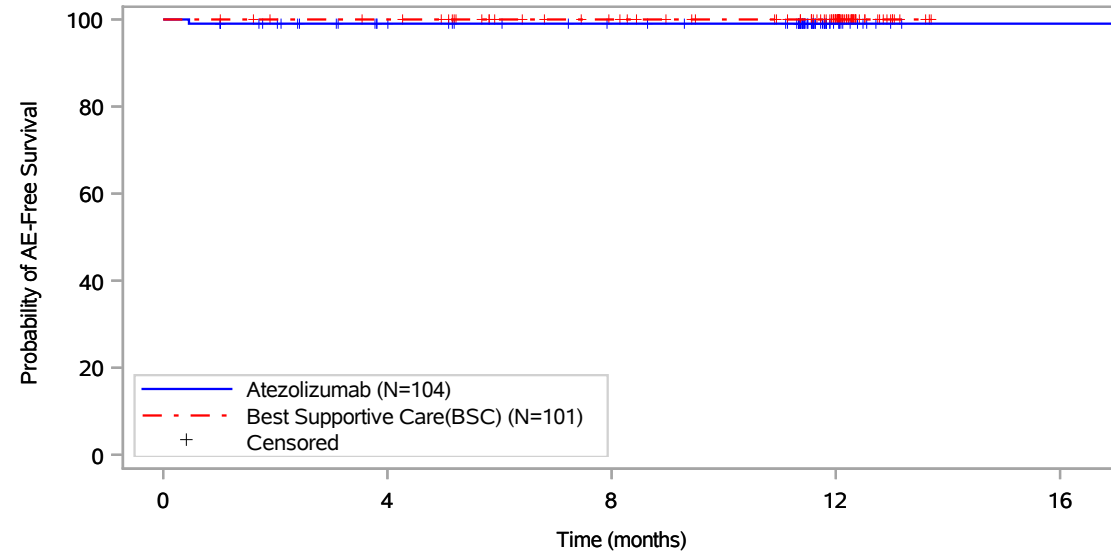
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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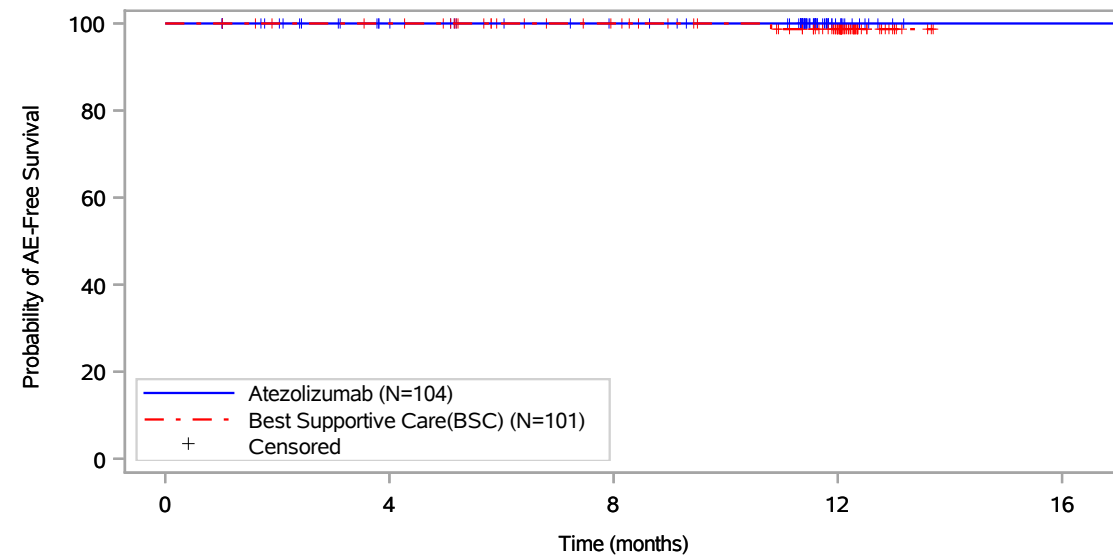
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Investigations, All



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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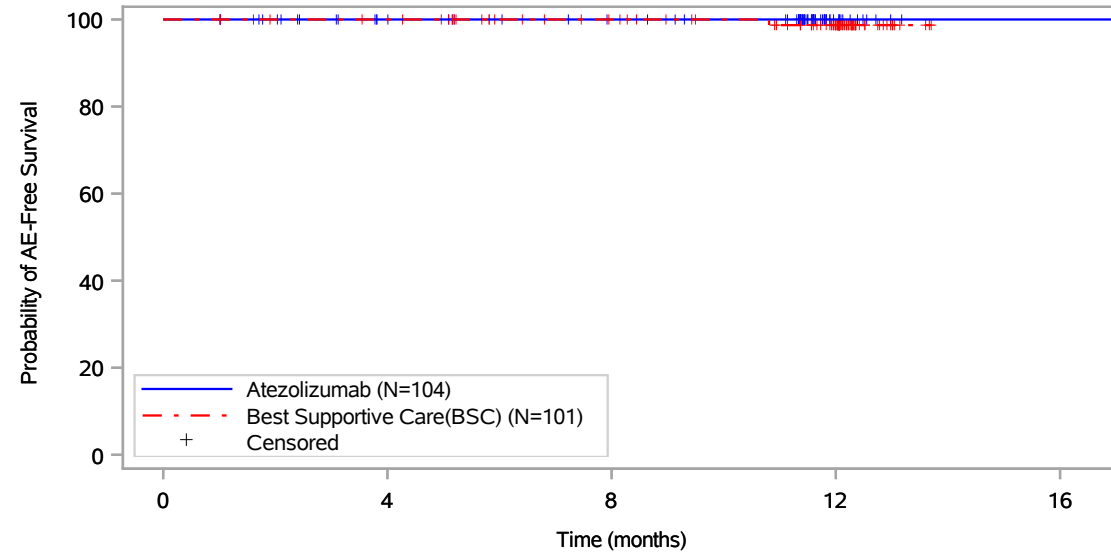
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Investigations, Neutrophil count decreased



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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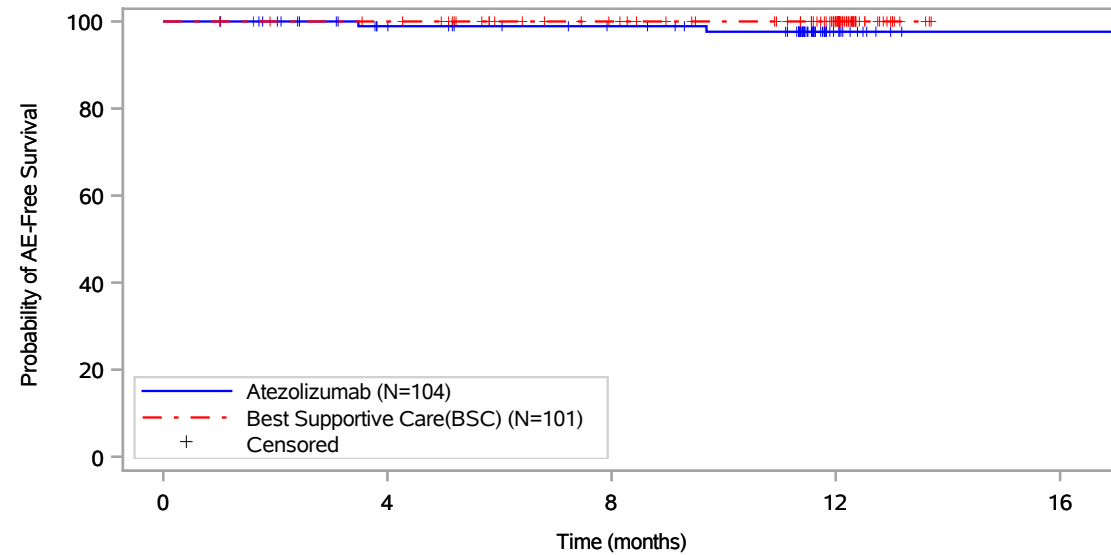
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	88	81	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	101
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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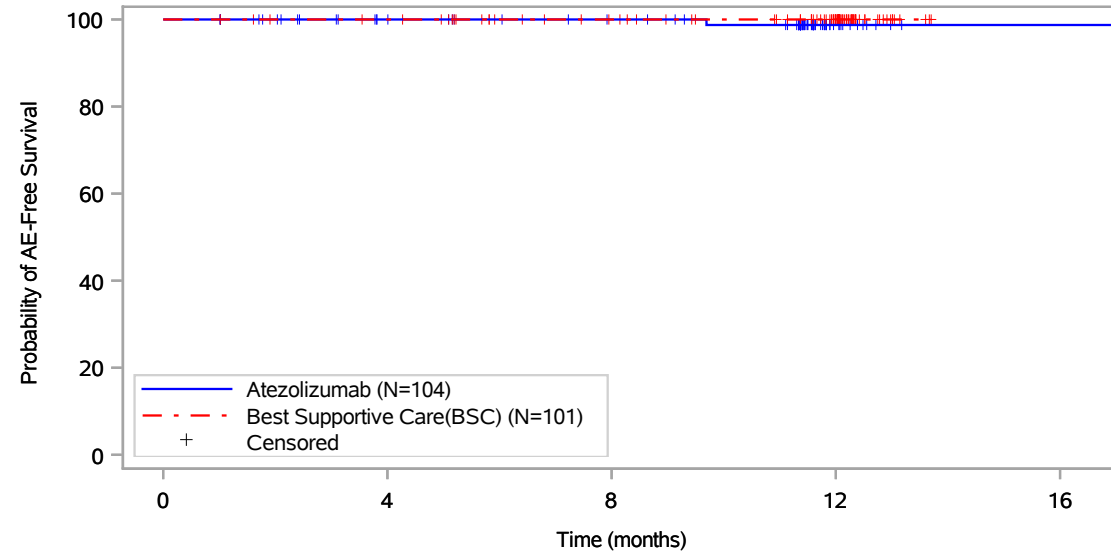
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk					
Atezolizumab (N=104)	104	89	82	12	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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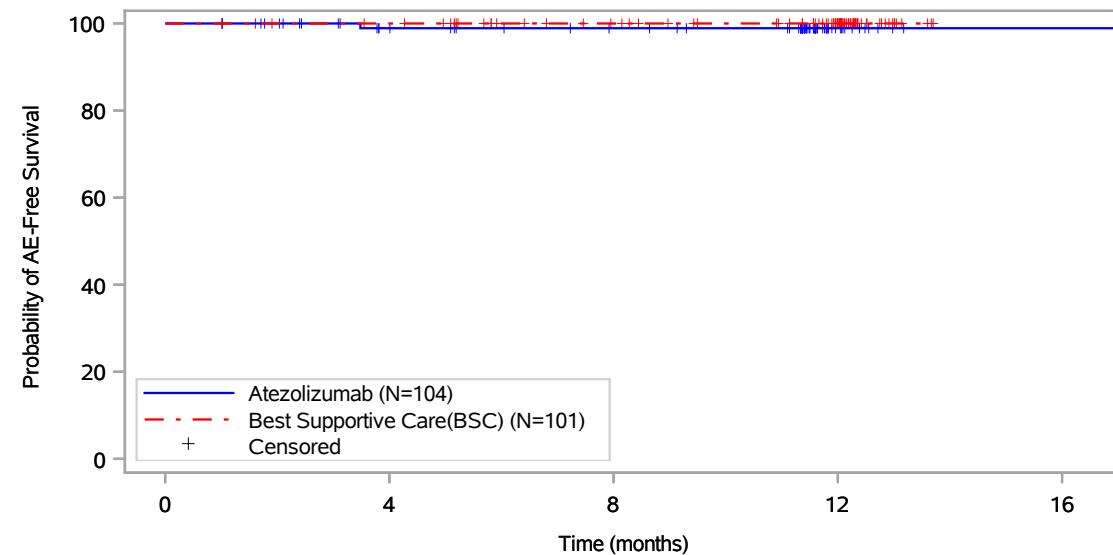
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



Patients at risk					
Atezolizumab (N=104)	104	88	81	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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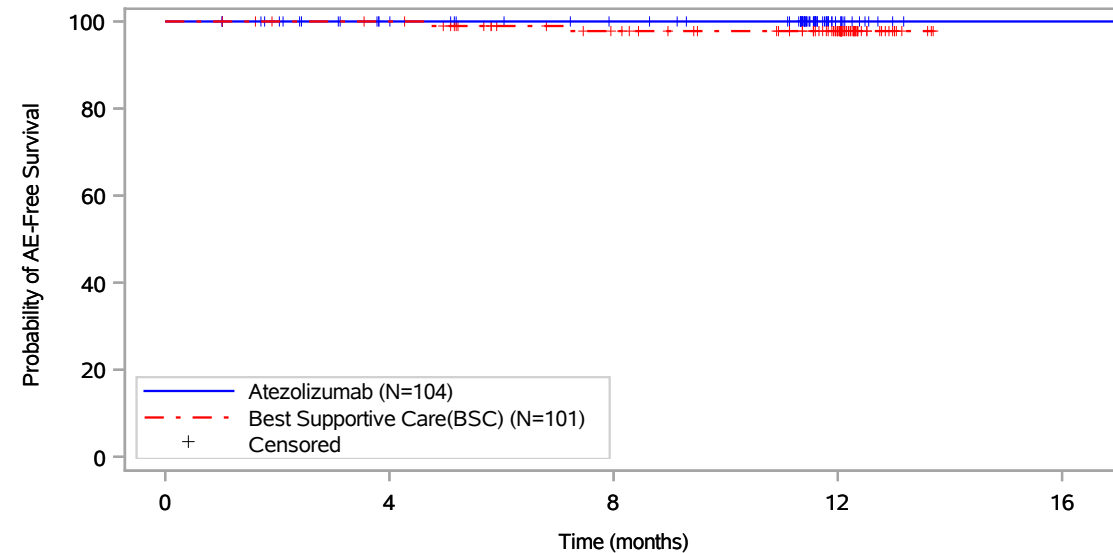
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Nervous system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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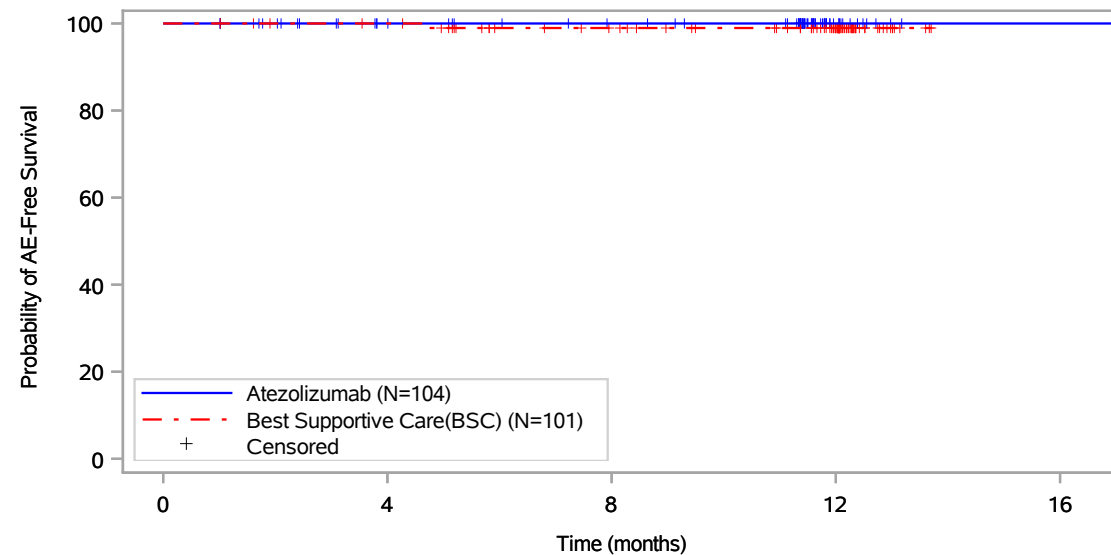
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Nervous system disorders, Brain oedema



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	17	45	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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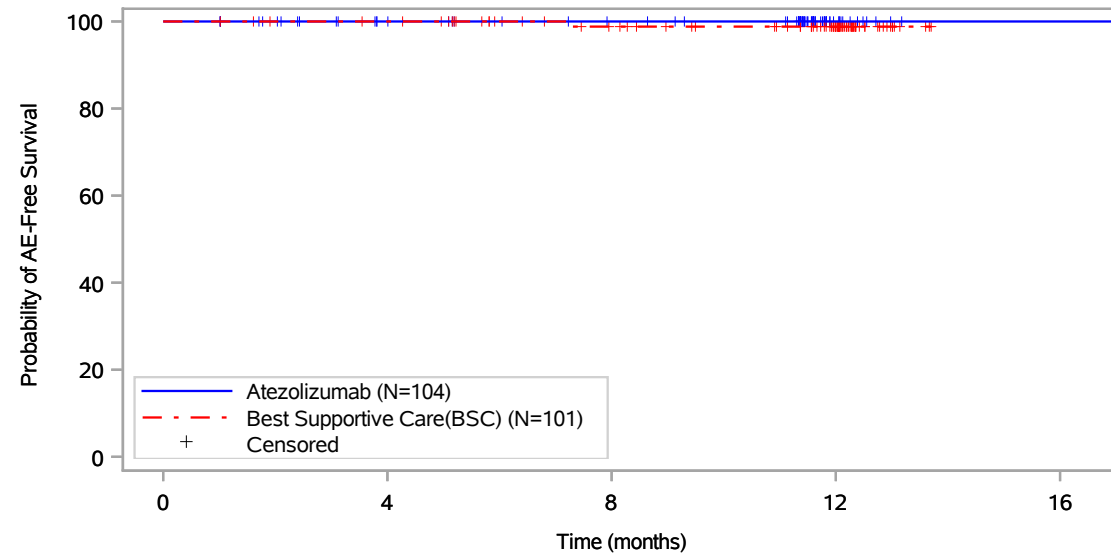
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	82	54	NE
Patients censored					
Atezolizumab (N=104)	0	15	22	91	103
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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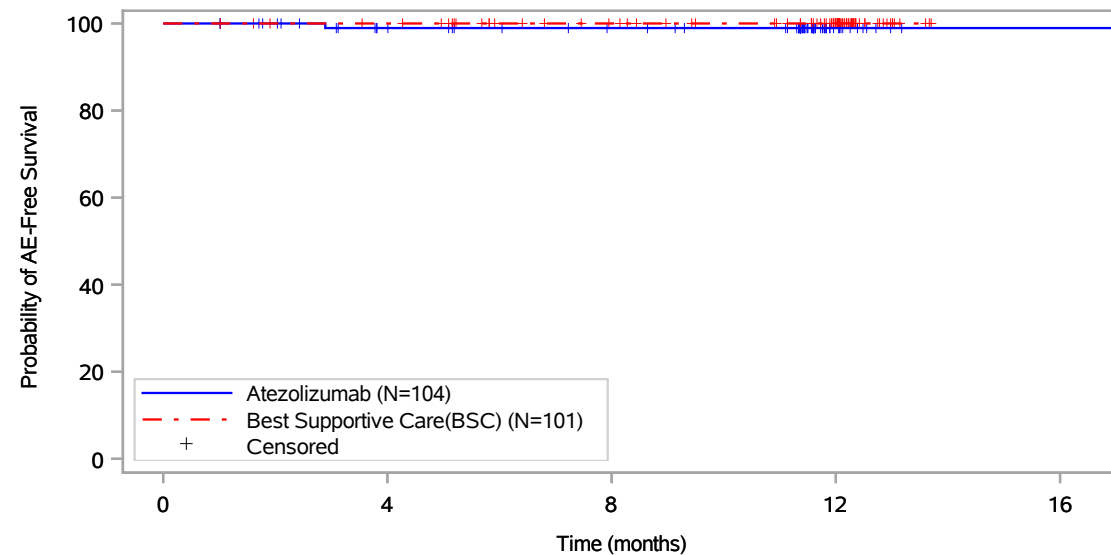
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..DFS_IA/prod/output/g_km_soc_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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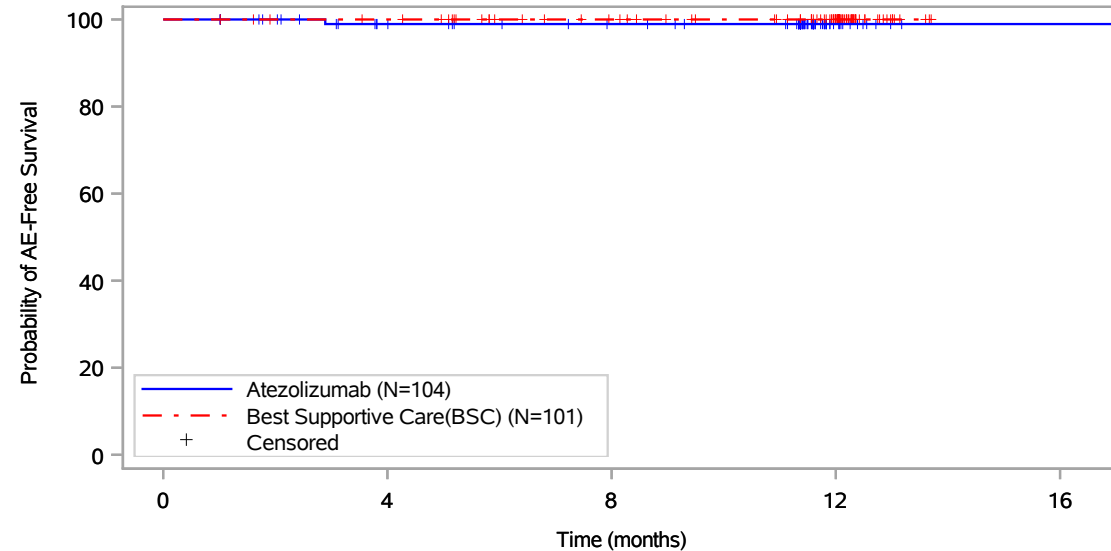
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk					
Atezolizumab (N=104)	104	89	82	13	1
Best Supportive Care(BSC) (N=101)	101	97	83	55	NE
Patients censored					
Atezolizumab (N=104)	0	14	21	90	102
Best Supportive Care(BSC) (N=101)	0	4	18	46	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
Output: ..DFS_IA/prod/output/g_km_soc_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
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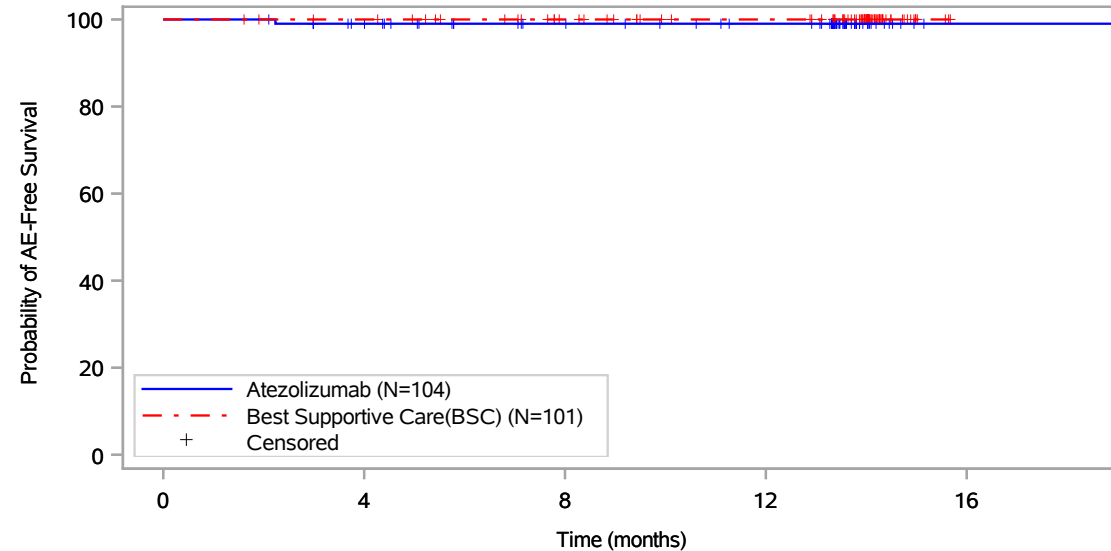
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Cardiac disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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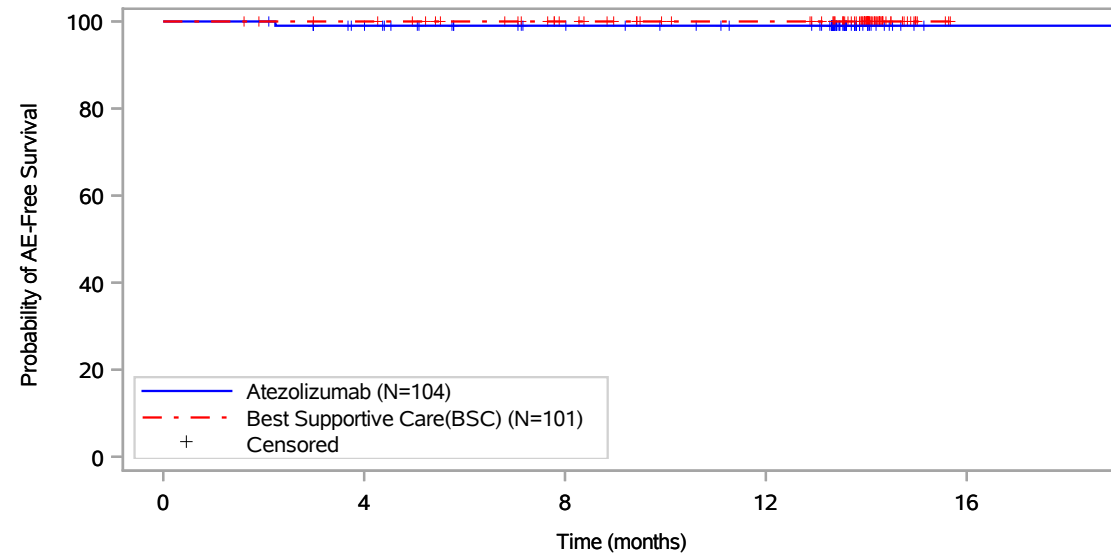
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Cardiac disorders, Atrial fibrillation



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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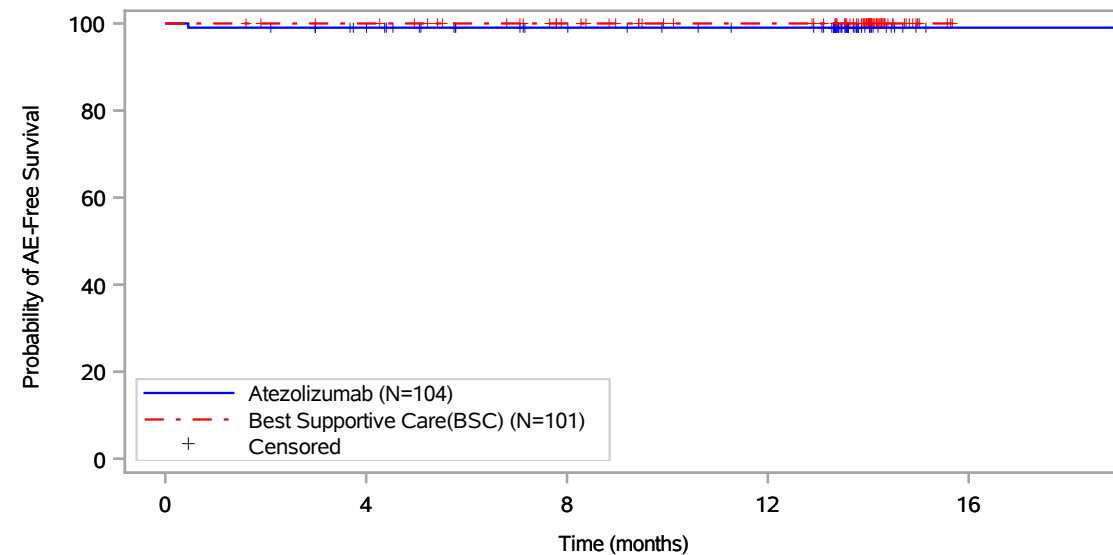
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Endocrine disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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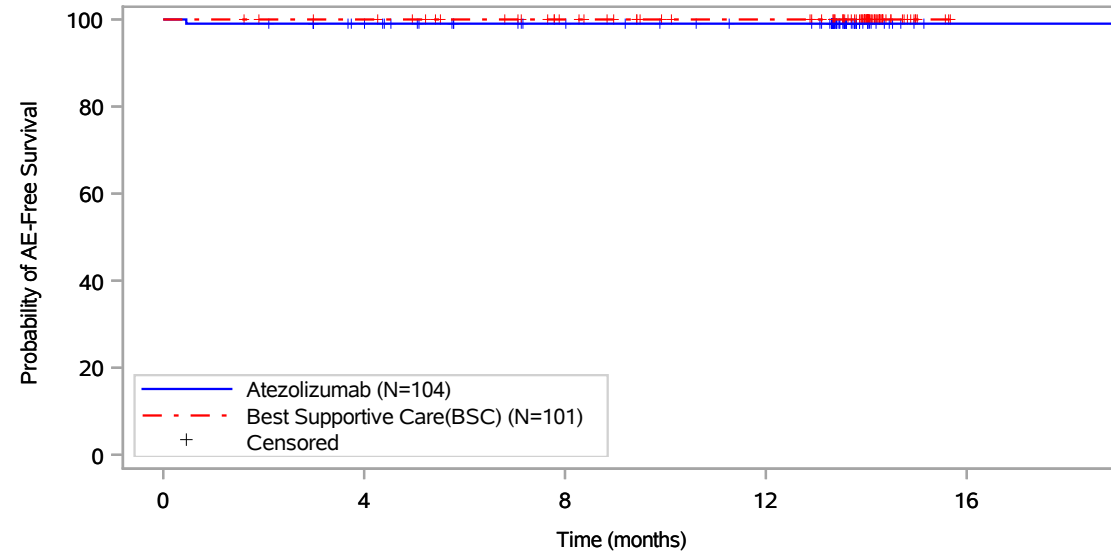
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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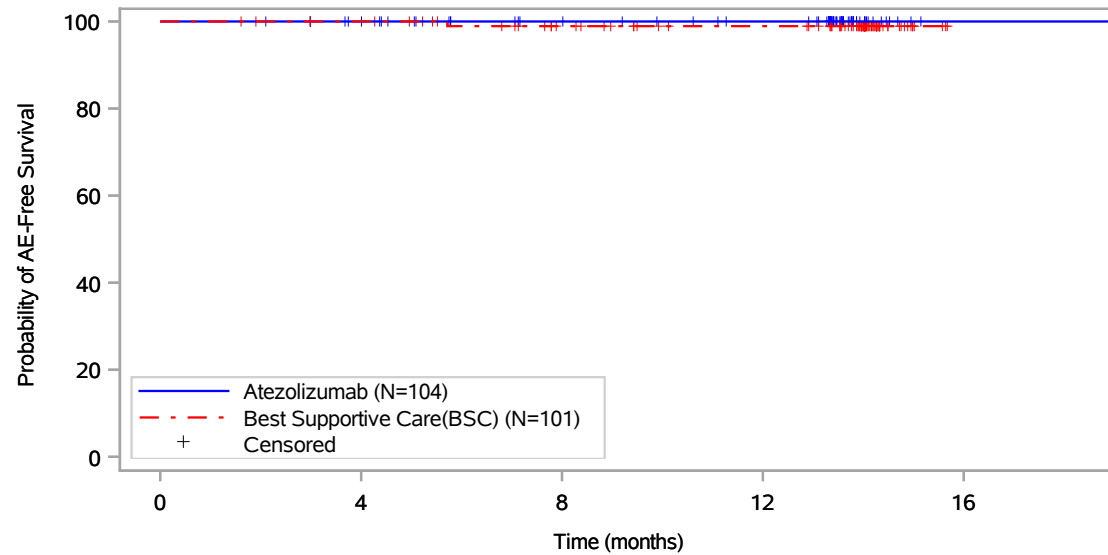
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Eye disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	85	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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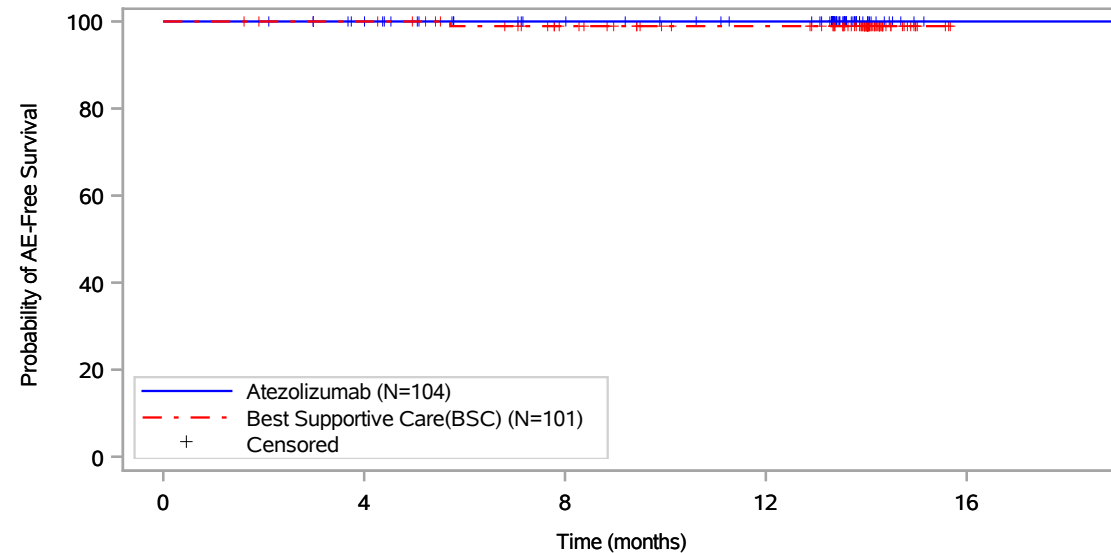
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Eye disorders, Vitreous haemorrhage



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	85	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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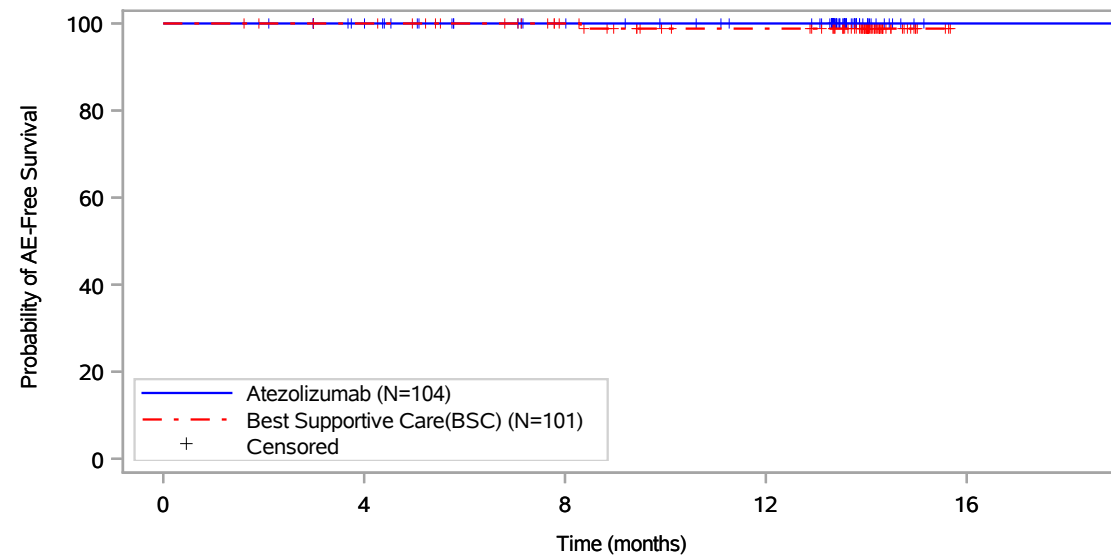
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Gastrointestinal disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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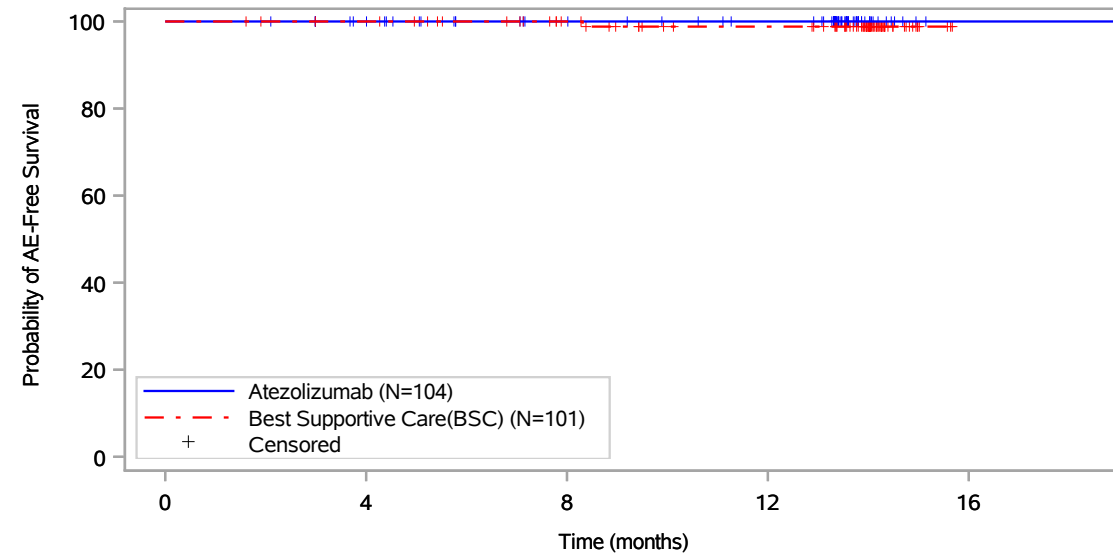
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal hernia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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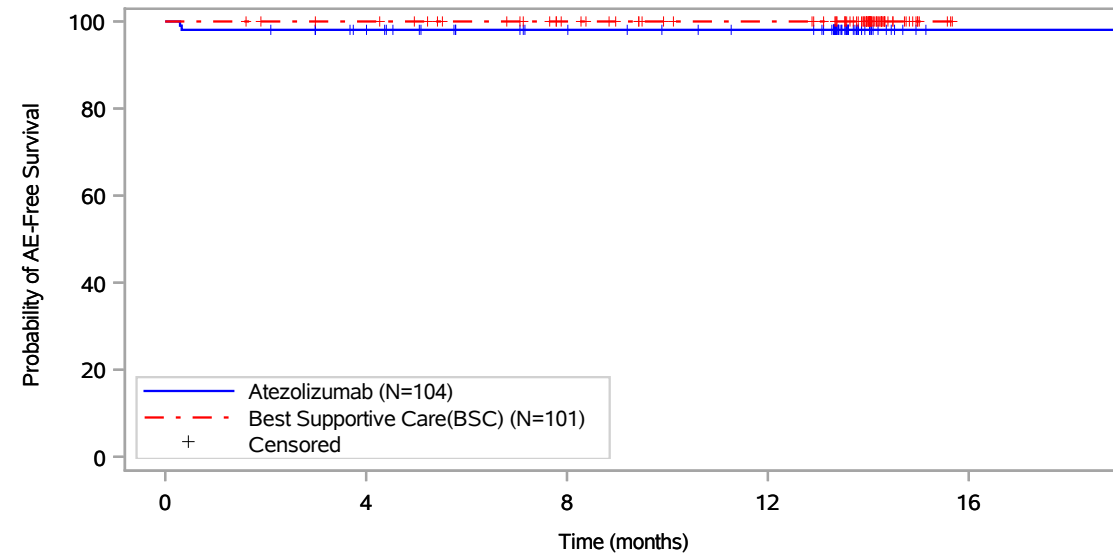
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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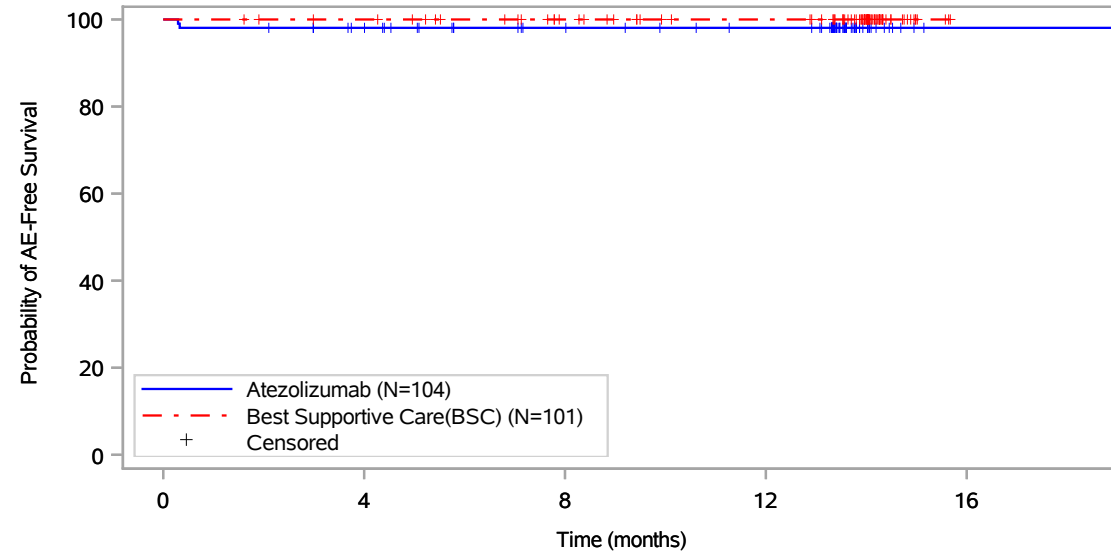
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

General disorders and administration site conditions, Pyrexia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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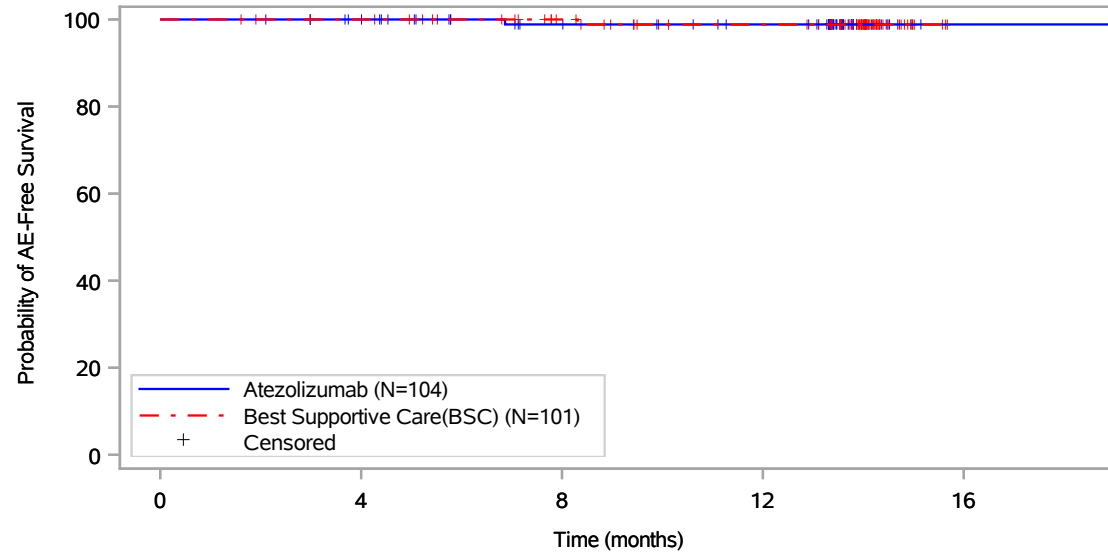
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Hepatobiliary disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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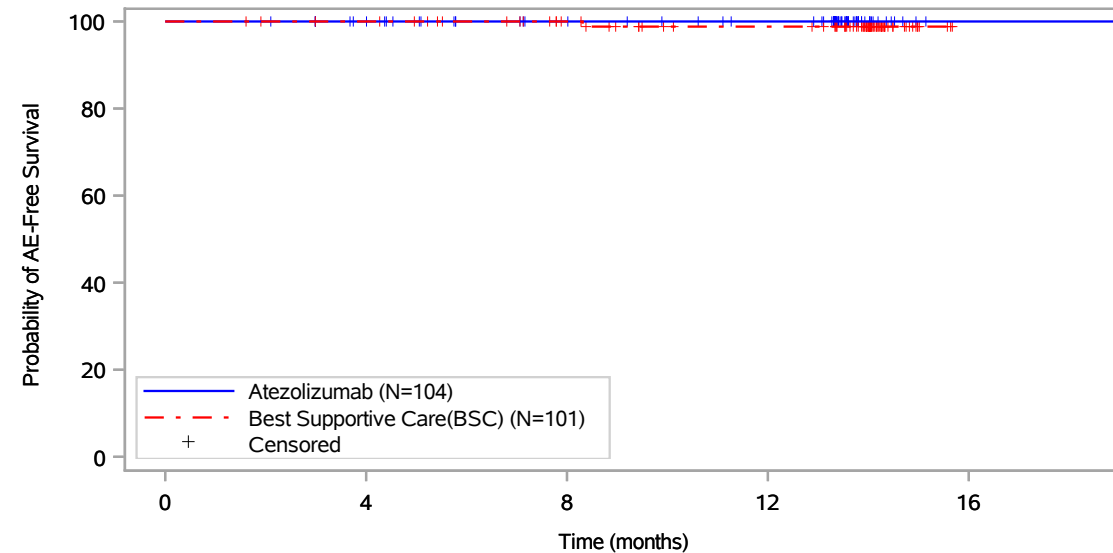
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Cholestasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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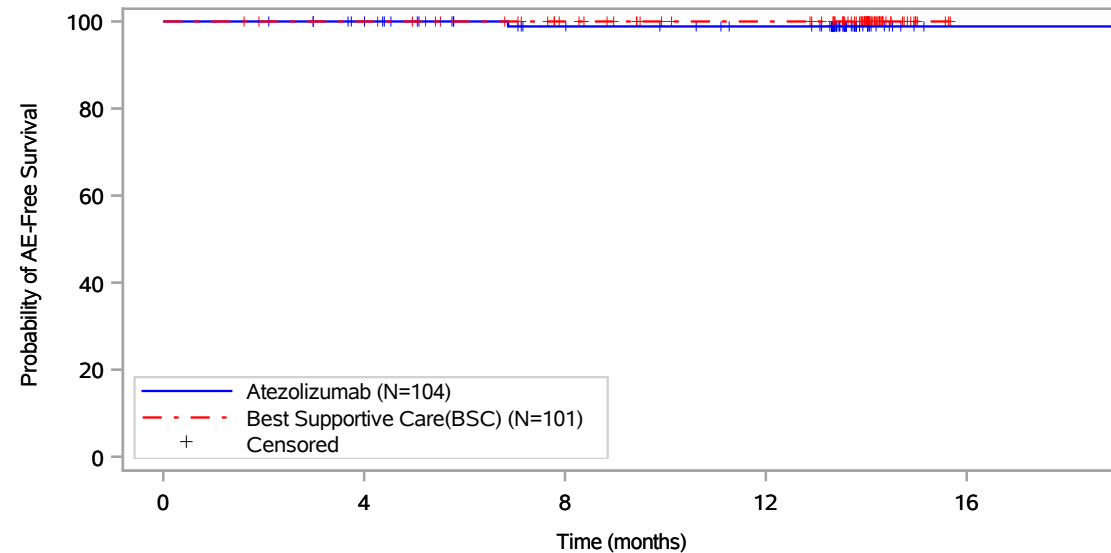
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Hepatobiliary disorders, Drug-induced liver injury



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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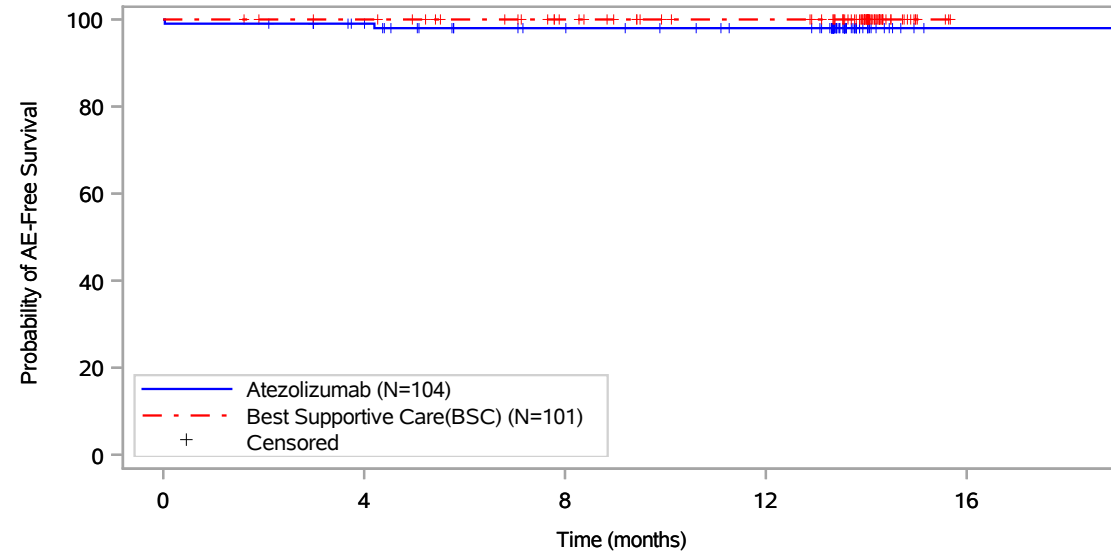
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Immune system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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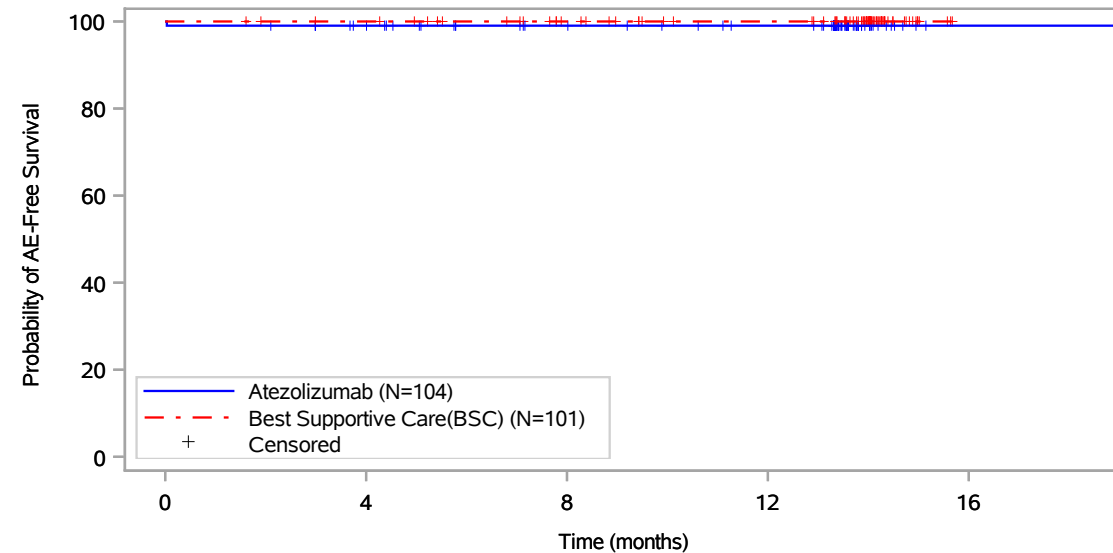
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Immune system disorders, Hypersensitivity



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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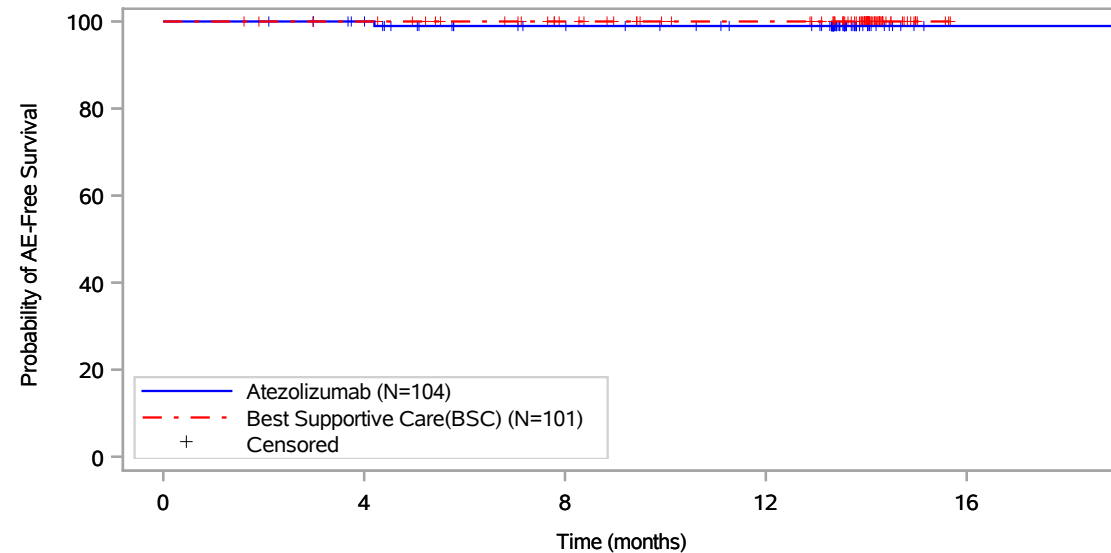
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Immune system disorders, Sarcoidosis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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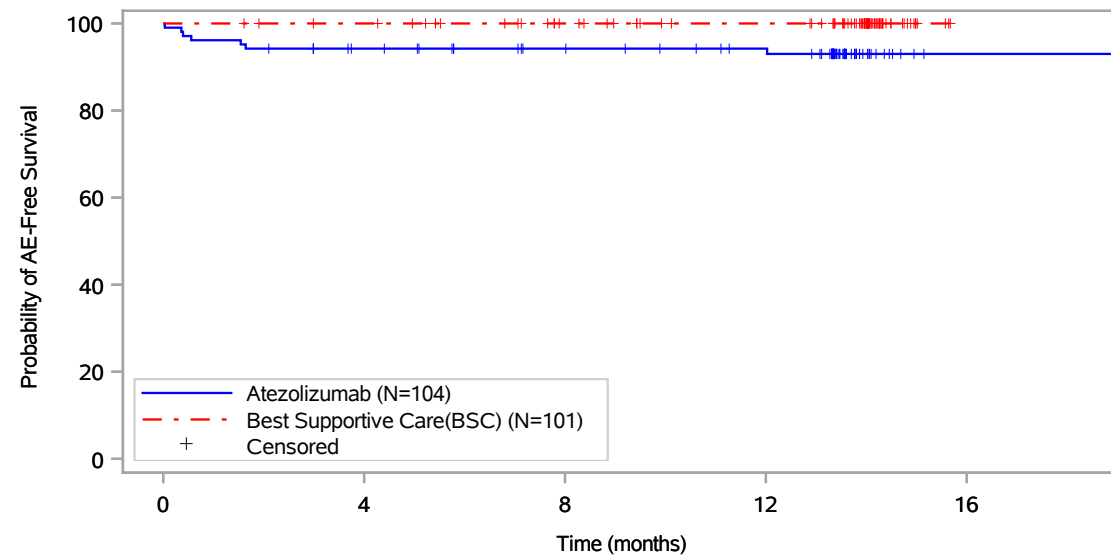
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	92	83	77	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	15	21	96
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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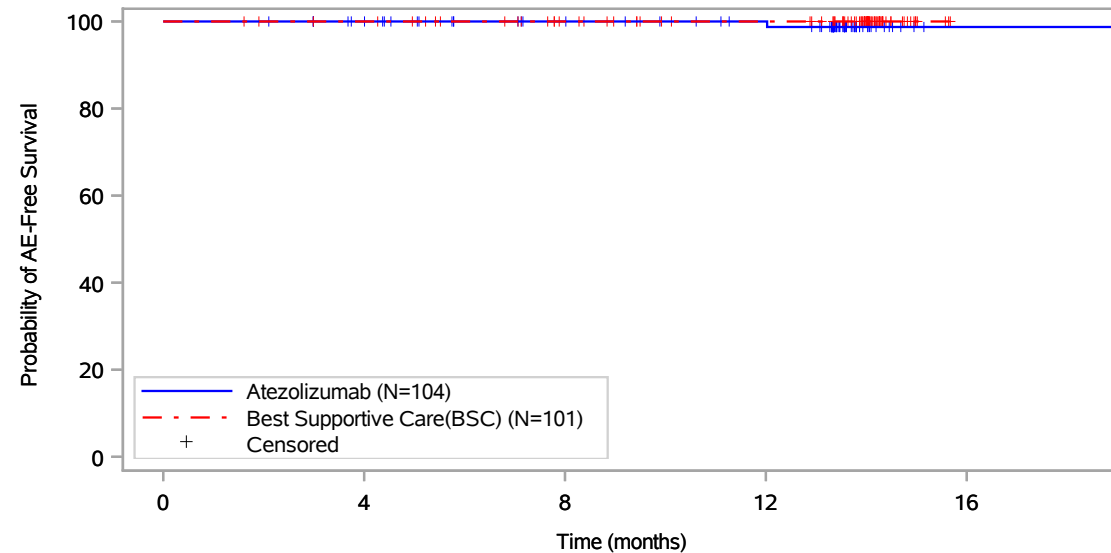
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Cellulitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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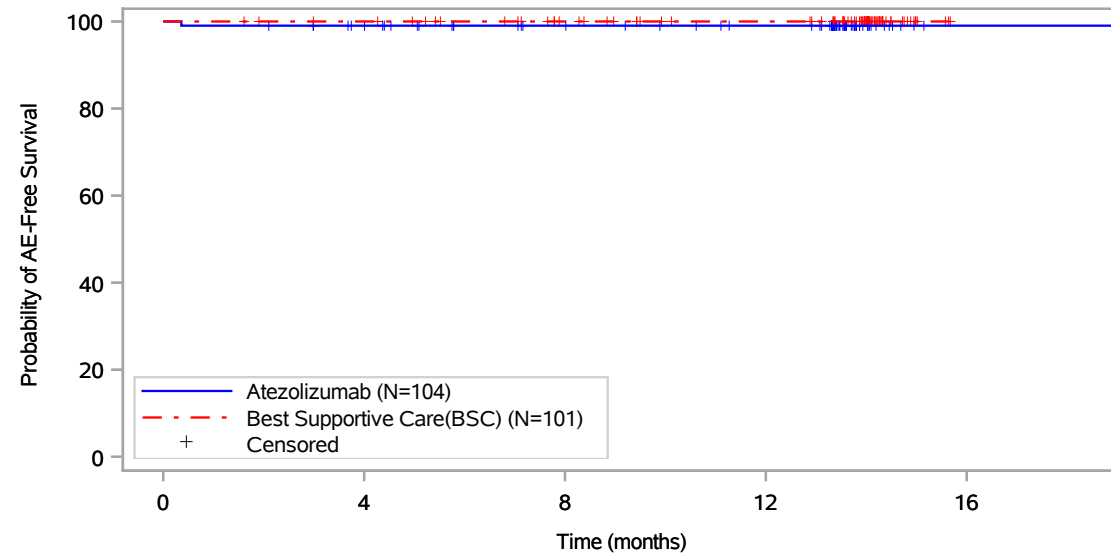
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Encephalitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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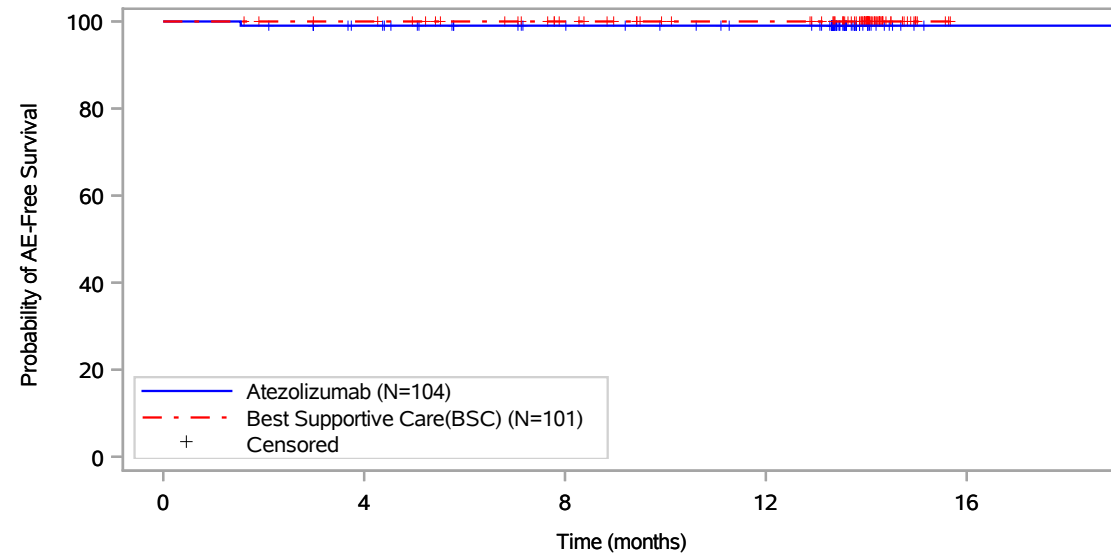
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Meningitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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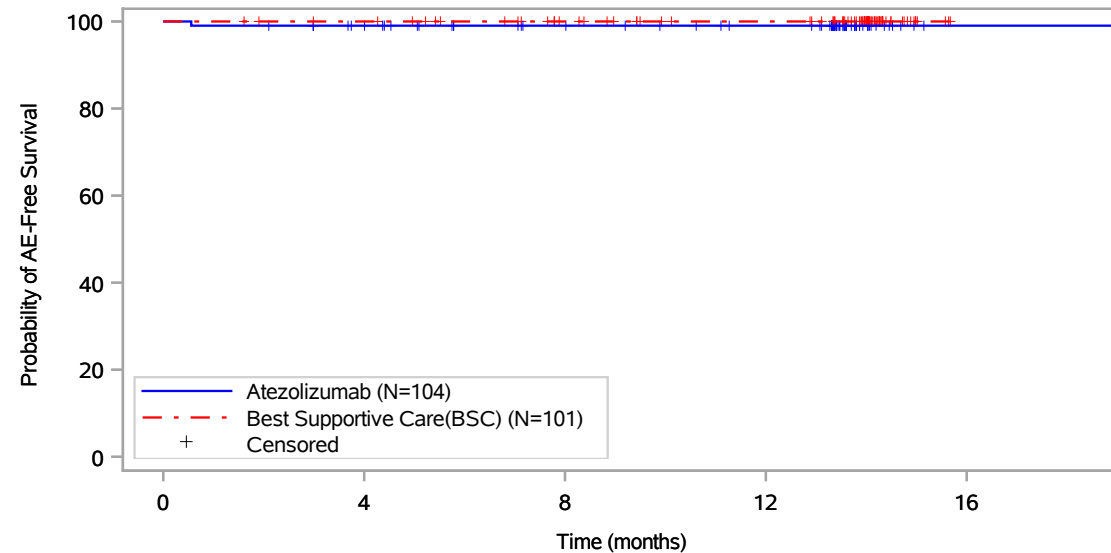
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Pneumonia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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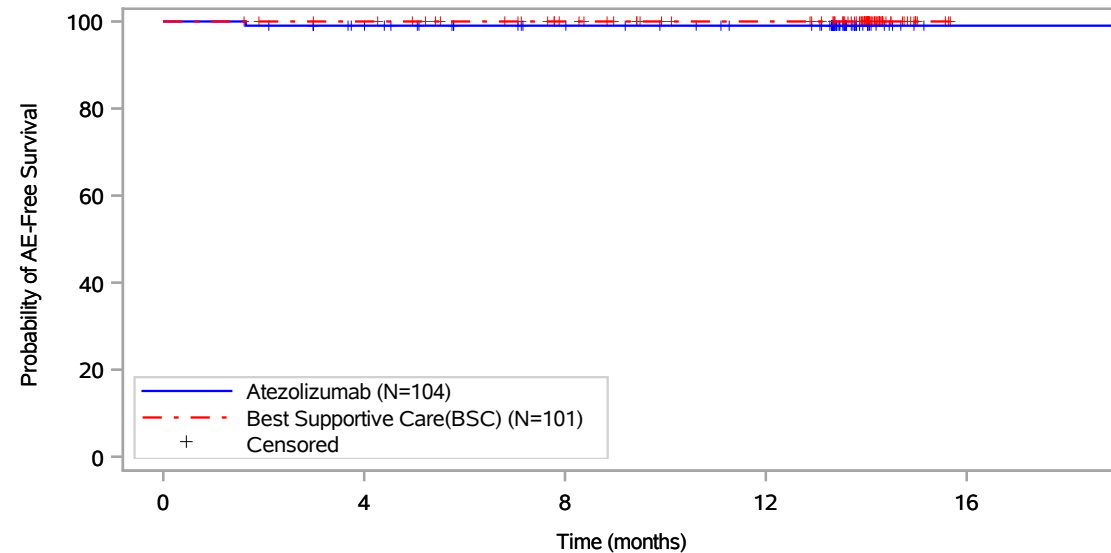
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Pneumonia pneumococcal



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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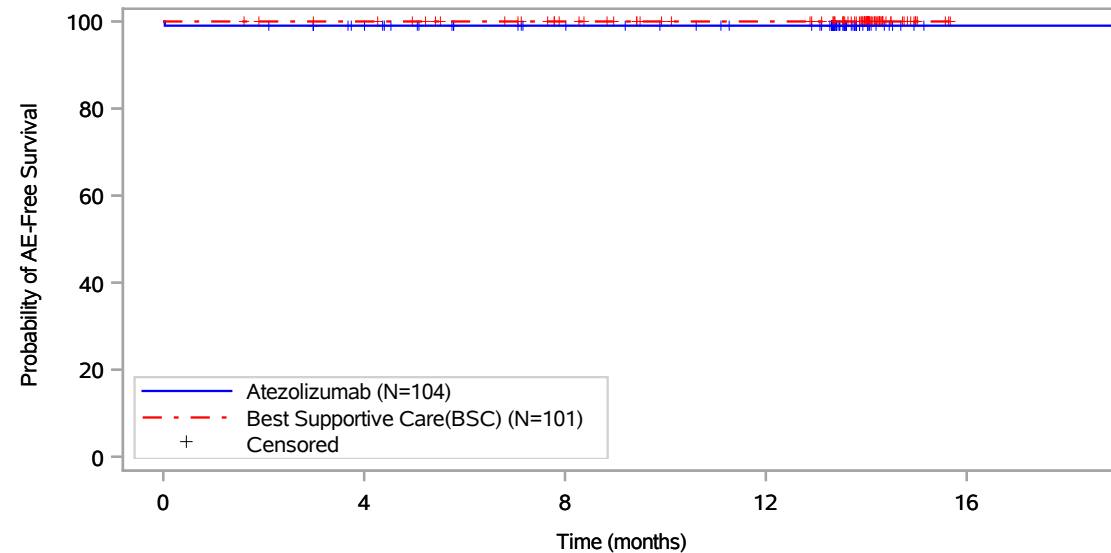
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Sepsis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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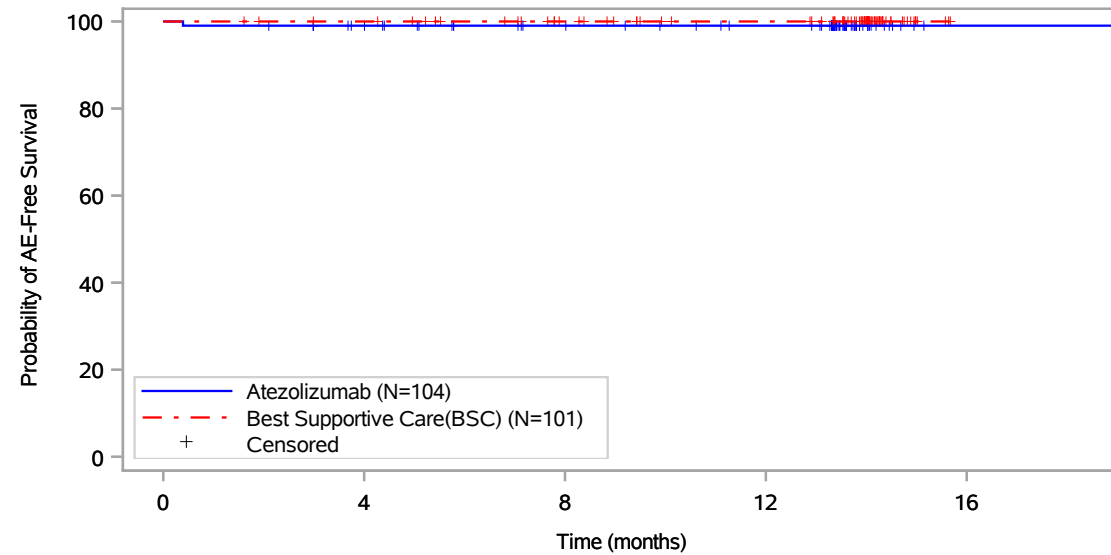
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Infections and infestations, Tonsillitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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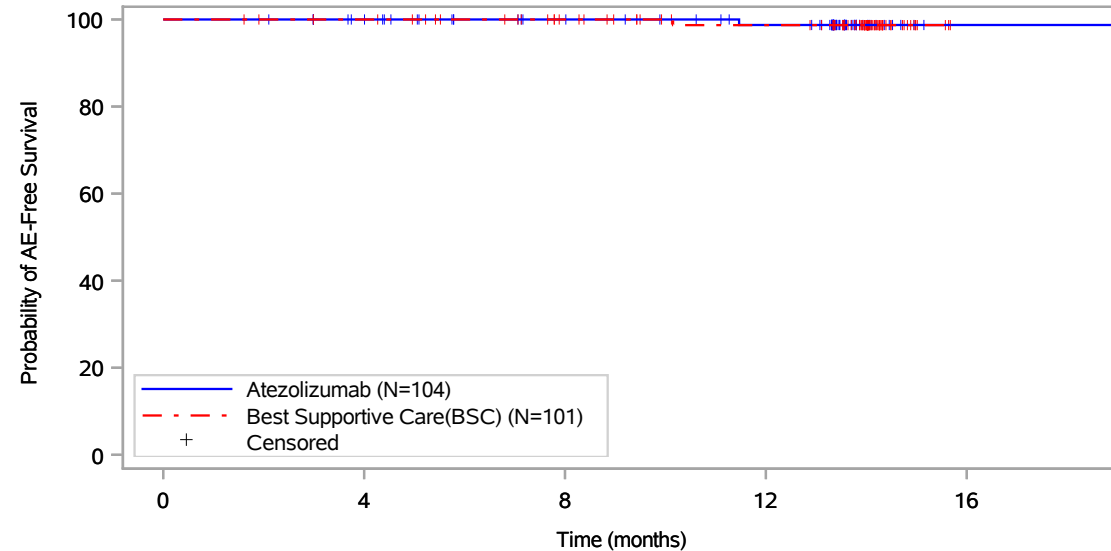
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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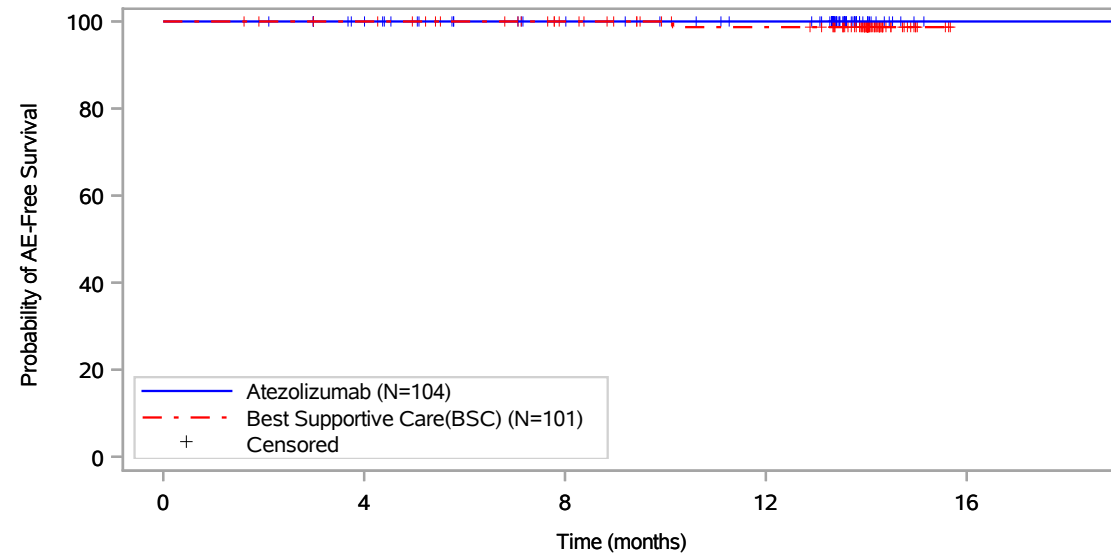
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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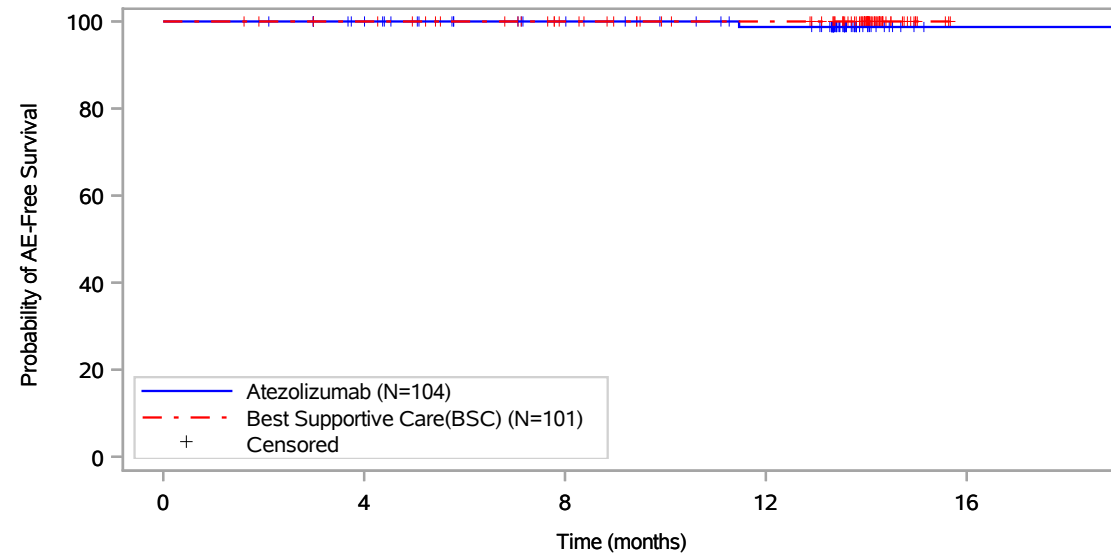
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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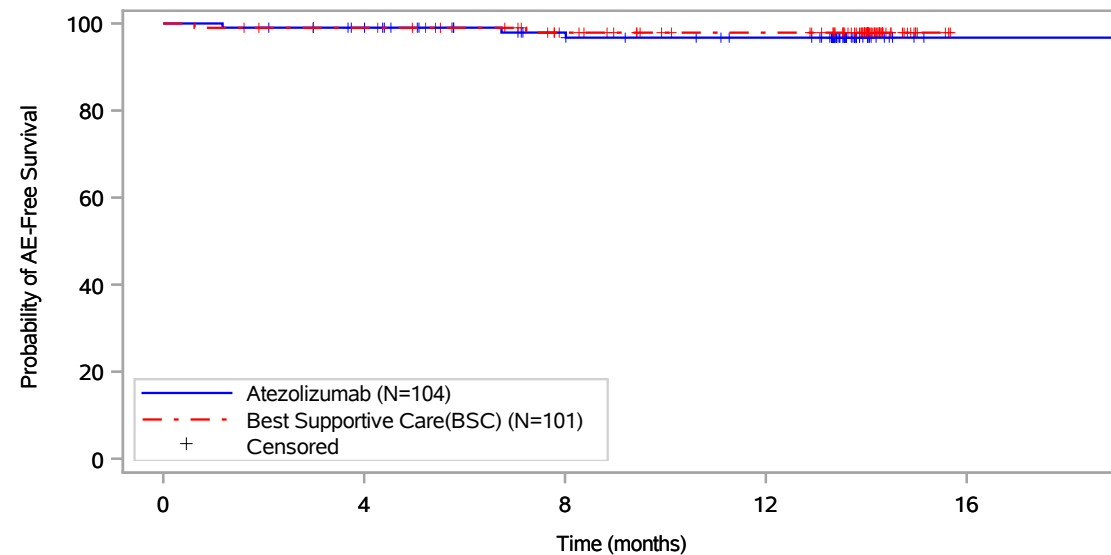
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	78	1
Best Supportive Care(BSC) (N=101)	101	97	84	75	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	23	100
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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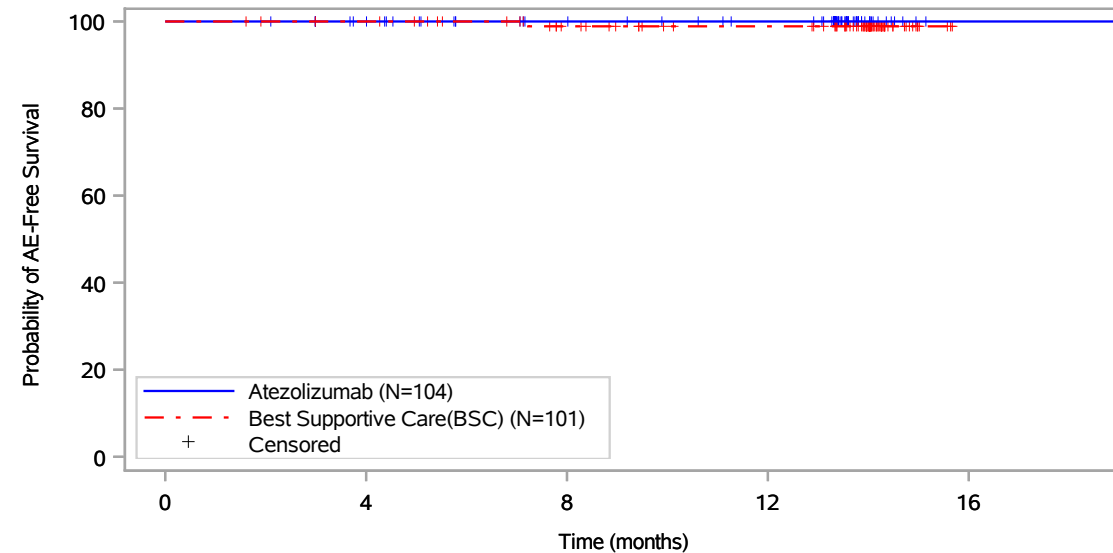
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	85	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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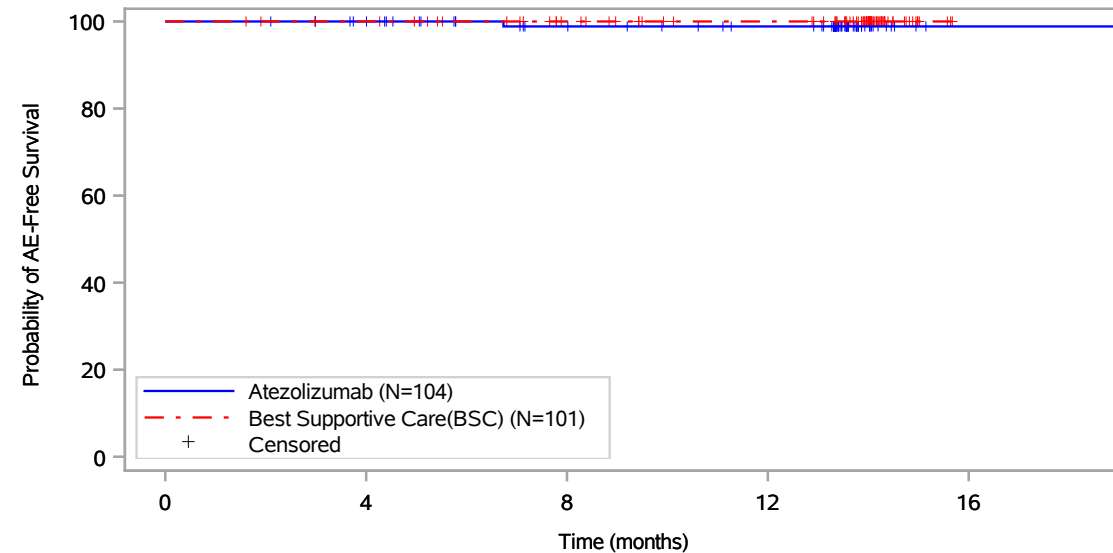
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Cerebral infarction



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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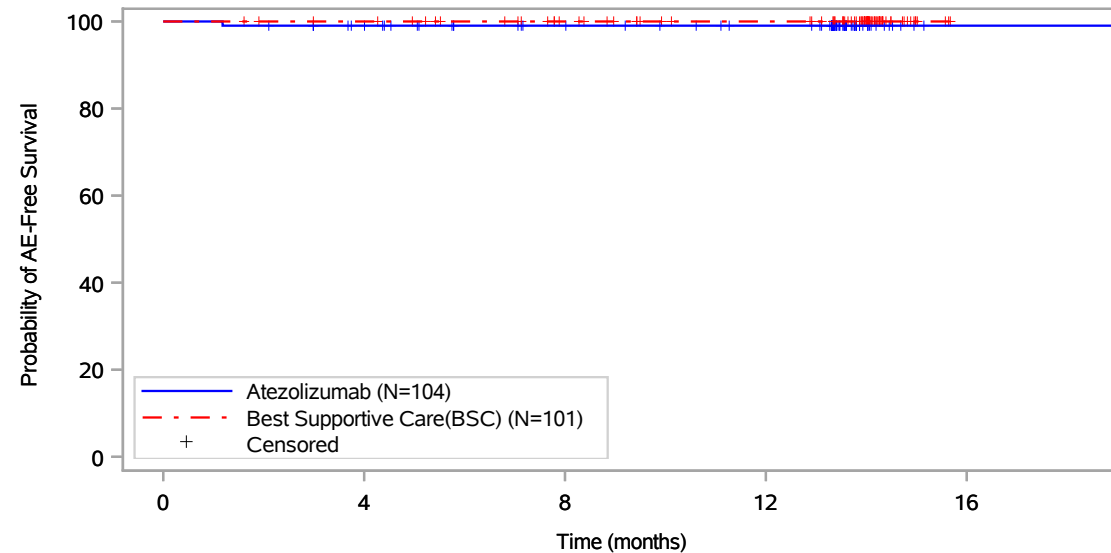
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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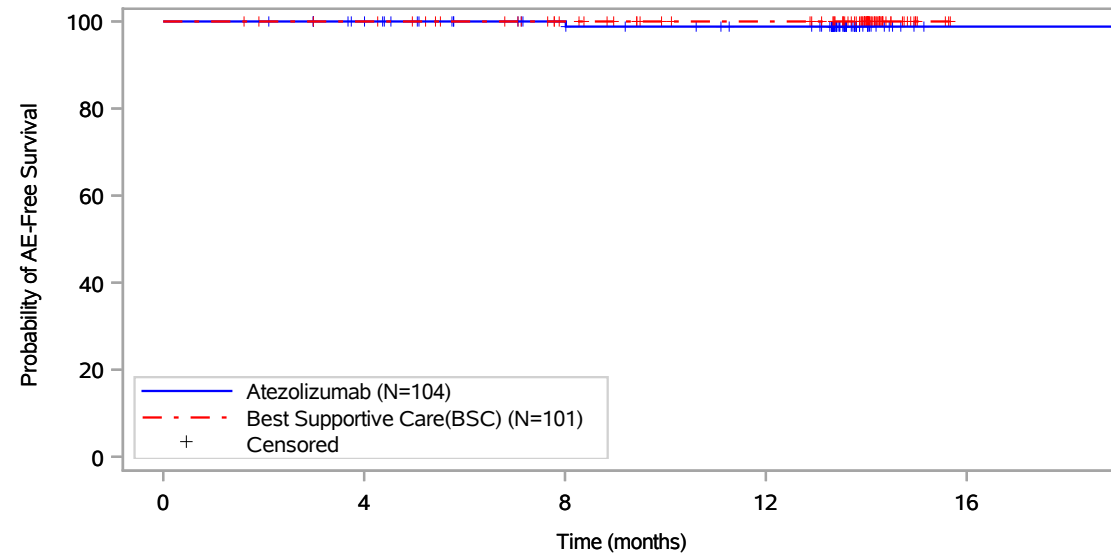
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Loss of consciousness



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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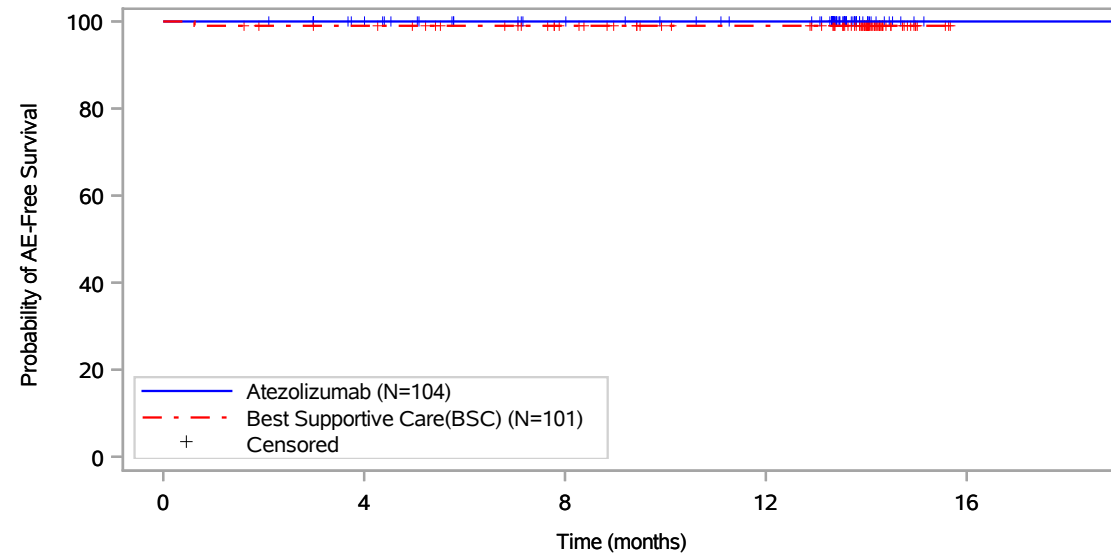
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Paraesthesia



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	97	85	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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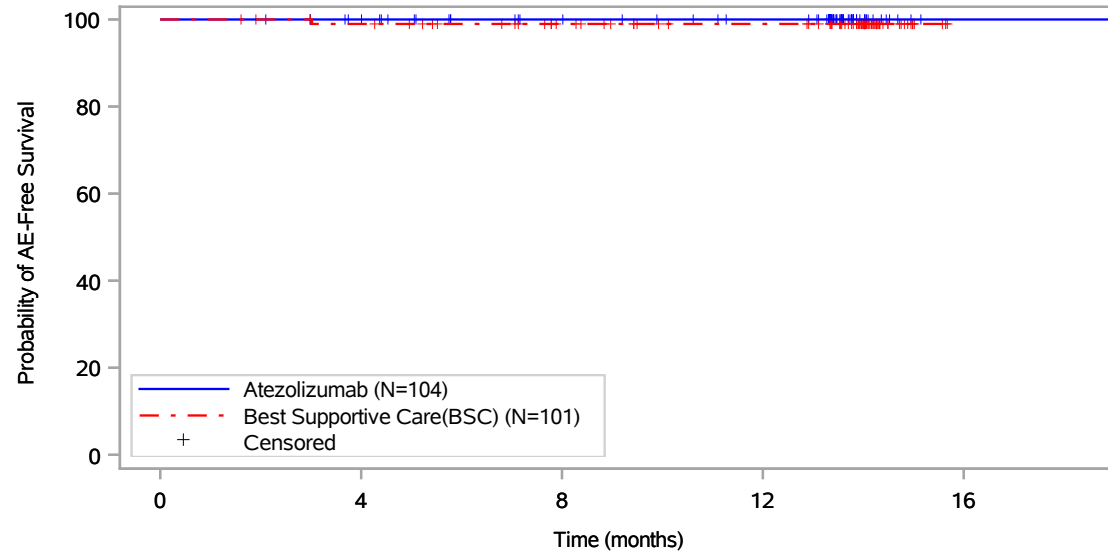
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	97	85	76	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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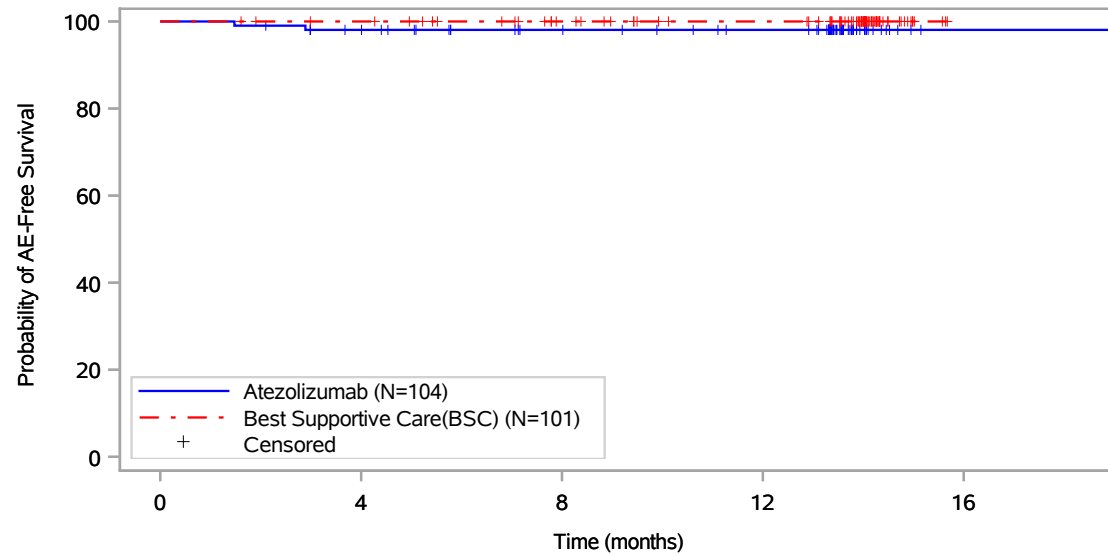
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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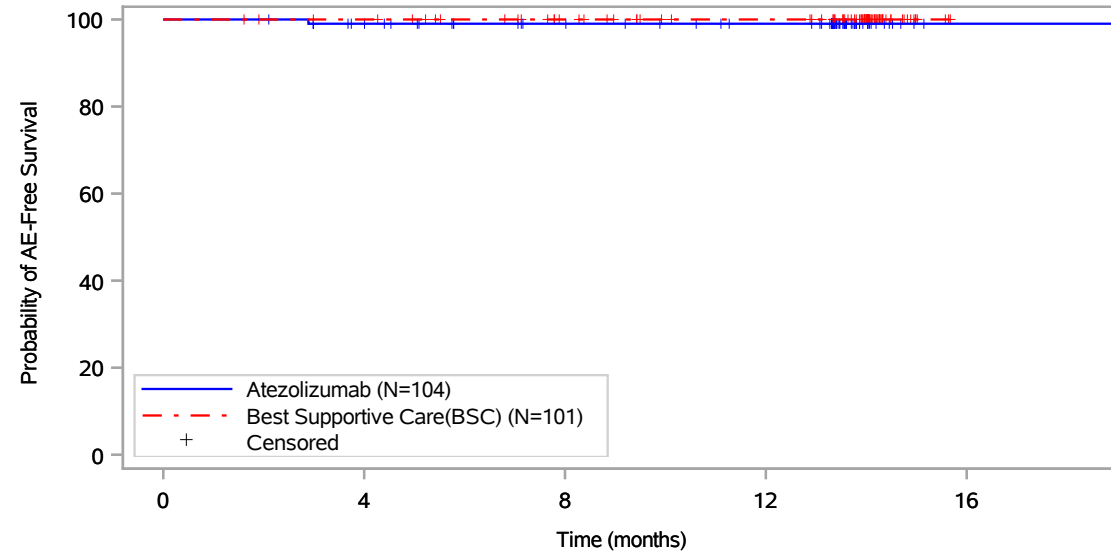
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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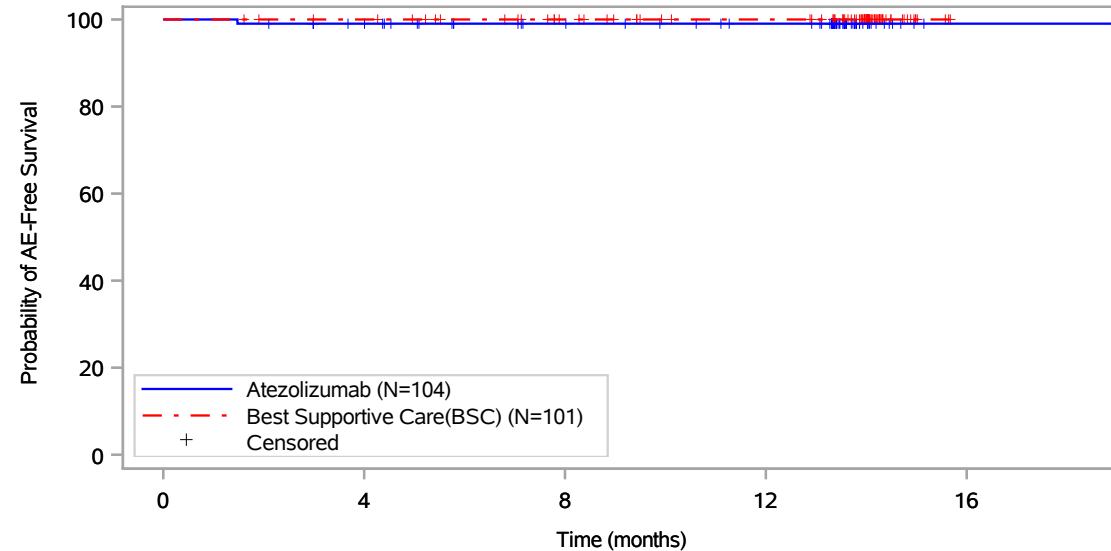
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pneumonitis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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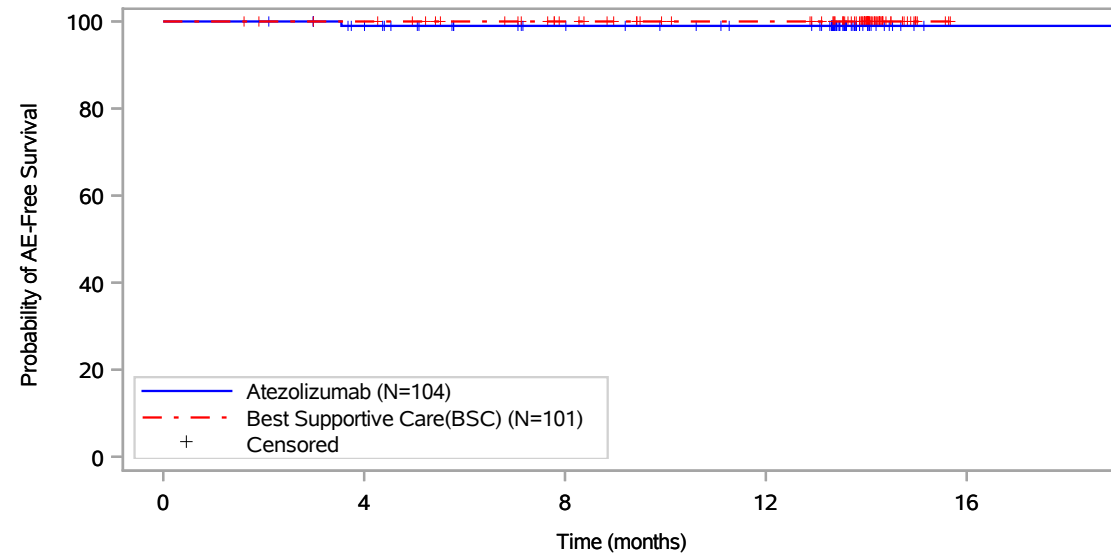
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

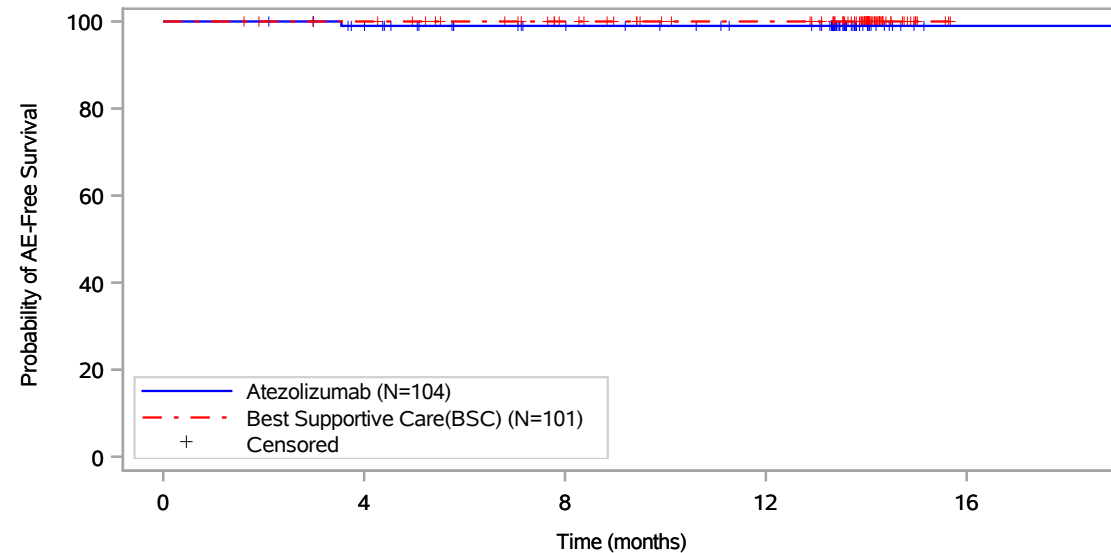
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Psoriasis



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

KM Plots

Subgruppen

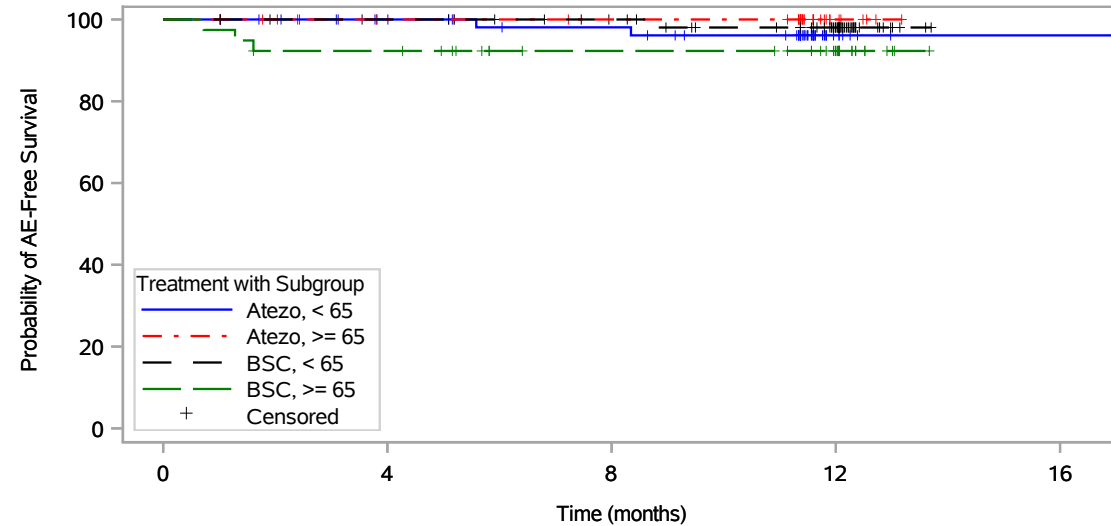
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Age at Randomization; Ear and labyrinth disorders, All (N=205)



Patients at risk	0	4	8	12	16
Atezo, < 65	64	55	50	7	1
Atezo, \geq 65	40	34	32	6	NE
BSC, < 65	62	59	53	34	NE
BSC, \geq 65	39	35	27	18	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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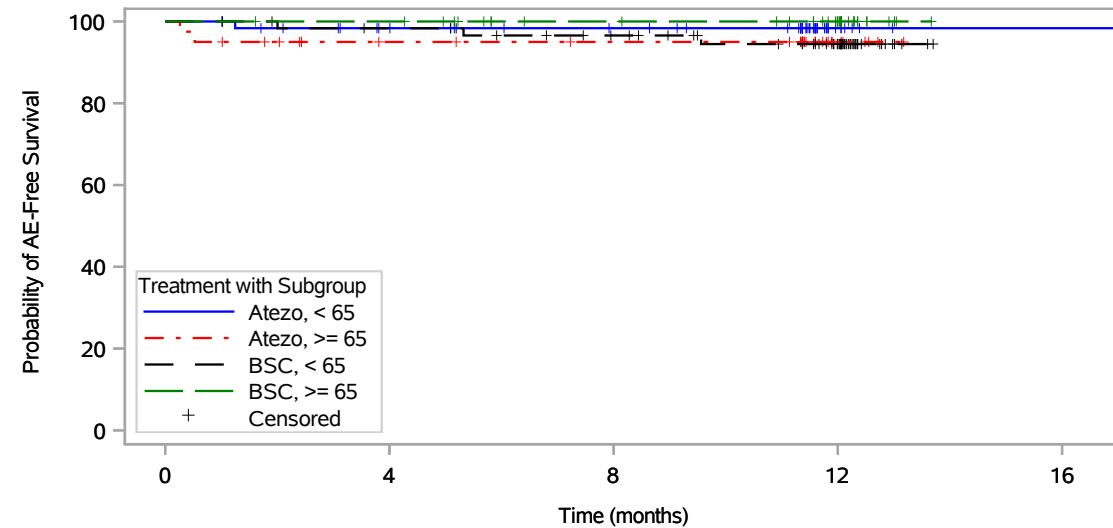
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Age at Randomization; Infections and infestations, Influenza (N=205)



Patients at risk	0	4	8	12	16
Atezo, < 65	64	54	49	7	1
Atezo, \geq 65	40	32	30	6	NE
BSC, < 65	62	58	51	33	NE
BSC, \geq 65	39	38	30	20	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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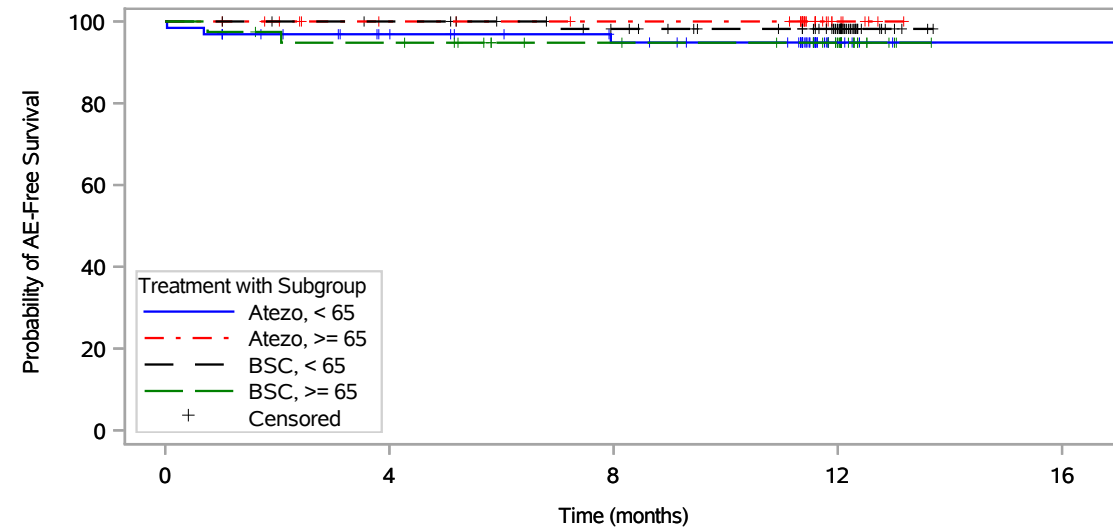
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Age at Randomization; Infections and infestations, Pharyngitis (N=205)



Patients at risk

Atezo, < 65	64	53	47	7	1
Atezo, \geq 65	40	34	32	6	NE
BSC, < 65	62	59	52	34	NE
BSC, \geq 65	39	36	29	20	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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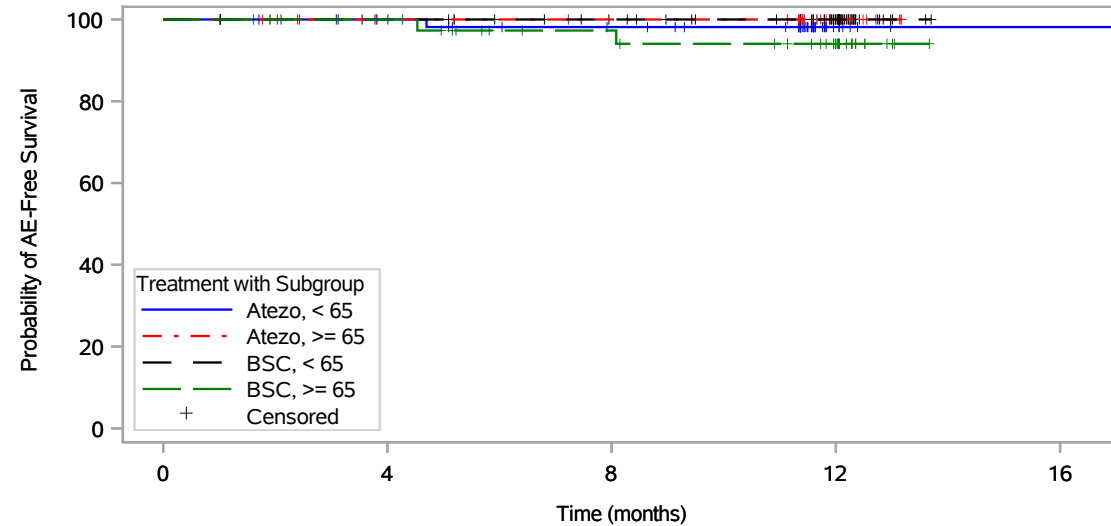
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Age at Randomization; Infections and infestations, Urinary tract infection (N=205)



Patients at risk	0	4	8	12	16
Atezo, < 65	64	55	49	7	1
Atezo, >= 65	40	34	32	6	NE
BSC, < 65	62	59	53	35	NE
BSC, >= 65	39	38	30	20	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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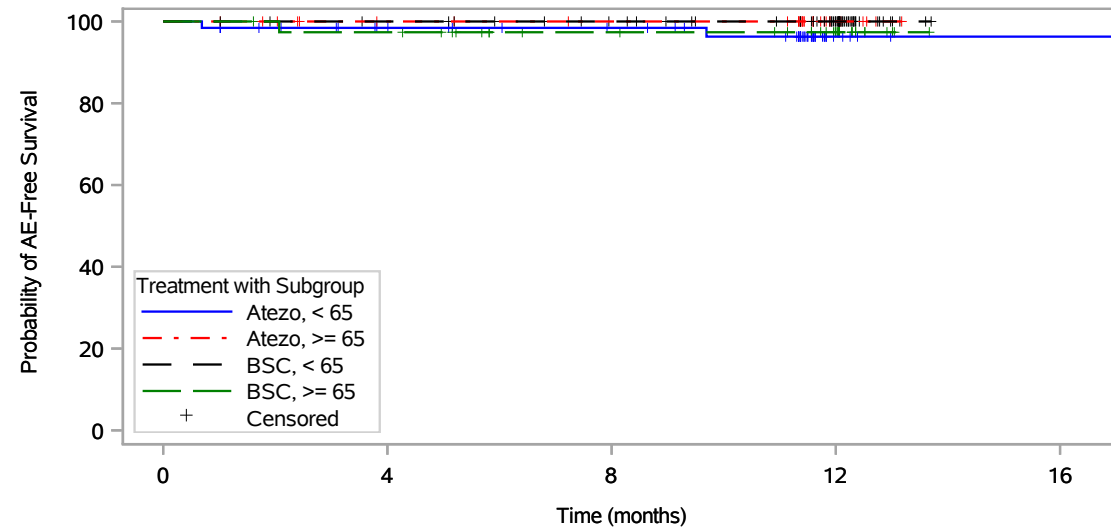
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Age at Randomization; Metabolism and nutrition disorders, Hypertriglyceridaemia (N=205)



Patients at risk	0	4	8	12	16
Atezo, < 65	64	54	49	5	1
Atezo, \geq 65	40	34	32	6	NE
BSC, < 65	62	59	53	35	NE
BSC, \geq 65	39	37	29	19	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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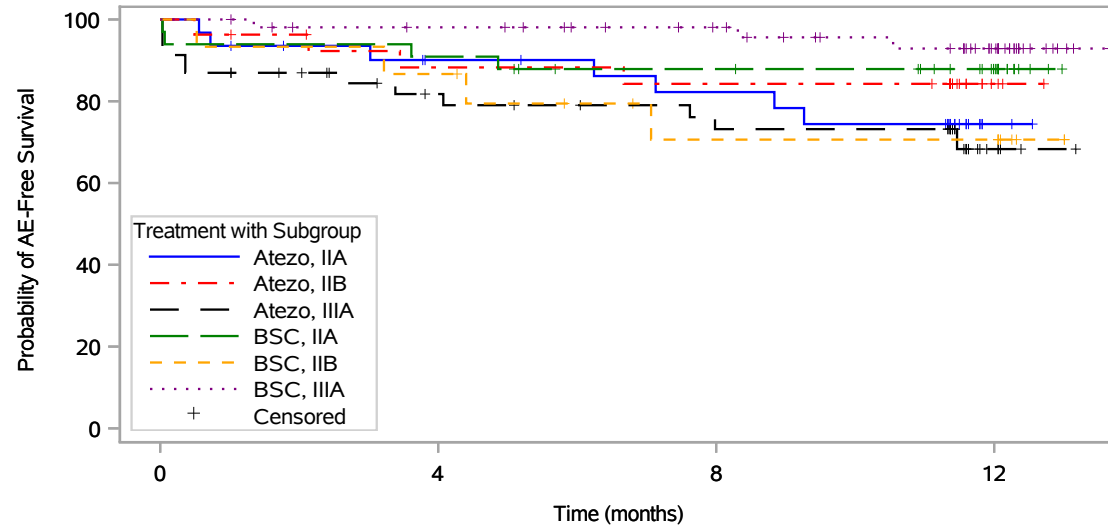
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Tumor stage; Gastrointestinal disorders, All (N=205)



Patients at risk

Atezo, IIA	31	24	21	2
Atezo, IIB	27	22	21	3
Atezo, IIIA	46	30	25	5
BSC, IIA	33	30	26	16
BSC, IIB	15	13	8	8
BSC, IIIA	53	48	41	24

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21 JAN 2021

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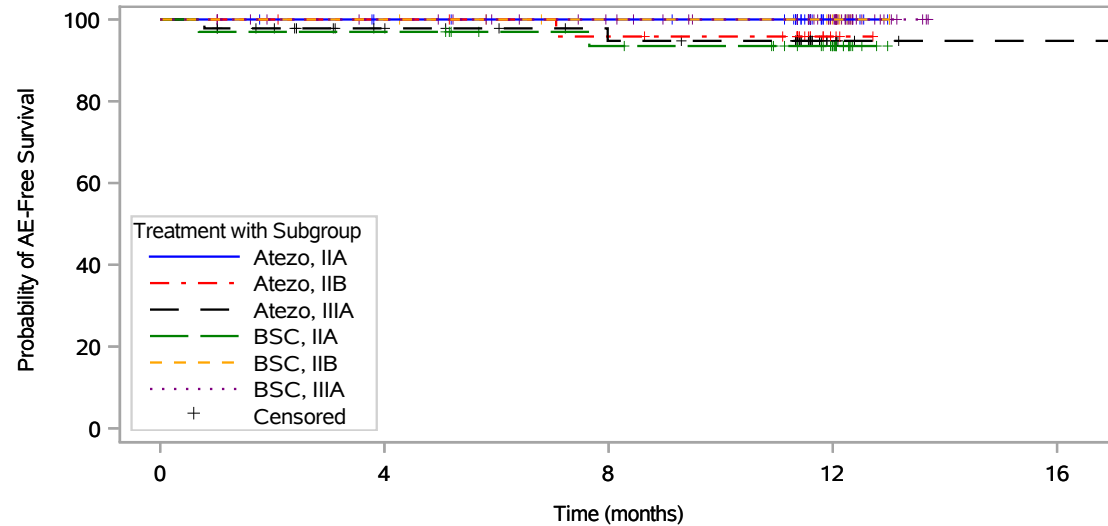
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Tumor stage; General disorders and administration site conditions, Fatigue (N=205)



Patients at risk	0	4	8	12	16
Atezo, IIA	31	27	26	4	NE
Atezo, IIB	27	25	23	3	NE
Atezo, IIIA	46	36	31	6	1
BSC, IIA	33	32	27	16	NE
BSC, IIB	15	15	12	10	NE
BSC, IIIA	53	49	42	27	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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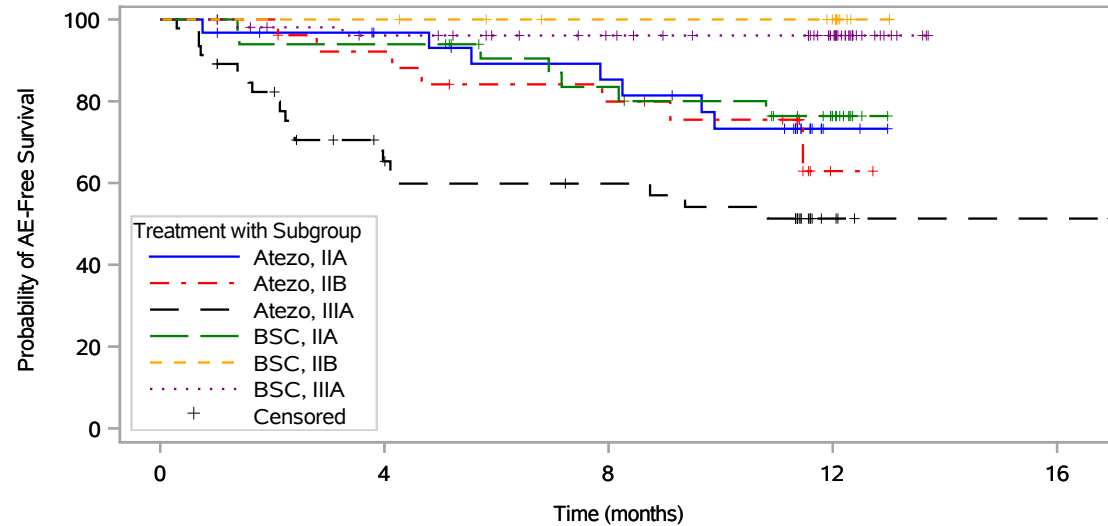
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Tumor stage; Investigations, All (N=205)



Patients at risk

Atezo, IIA	31	26	22	2	NE
Atezo, IIB	27	23	19	1	NE
Atezo, IIIA	46	25	21	4	1
BSC, IIA	33	31	24	13	NE
BSC, IIB	15	15	12	10	NE
BSC, IIIA	53	47	40	27	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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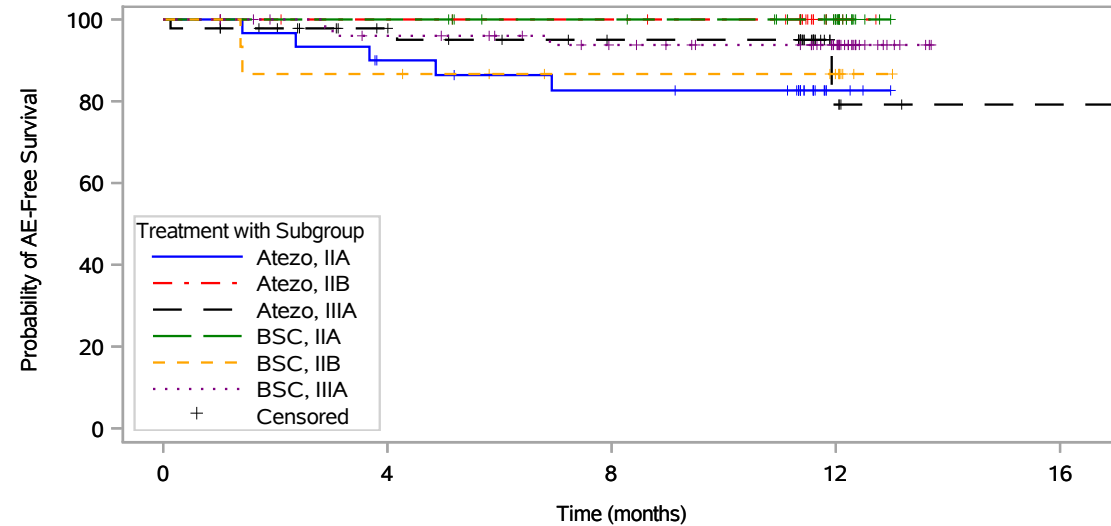
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Tumor stage; Respiratory, thoracic and mediastinal disorders, Dyspnoea (N=205)



Patients at risk	0	4	8	12	16
Atezo, IIA	31	25	22	3	NE
Atezo, IIB	27	25	24	3	NE
Atezo, IIIA	46	36	30	5	1
BSC, IIA	33	33	29	18	NE
BSC, IIB	15	13	10	8	NE
BSC, IIIA	53	47	40	26	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21 JAN 2021

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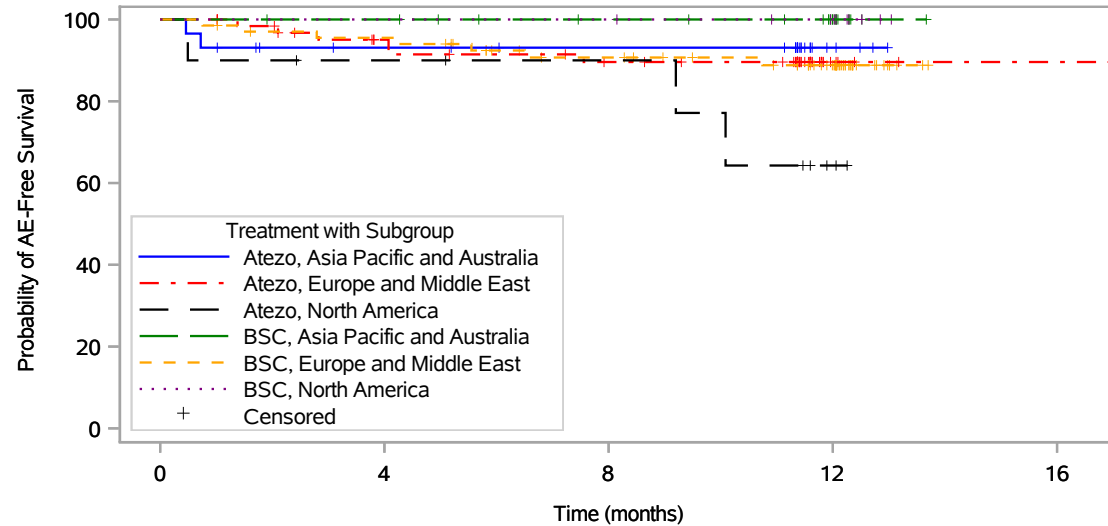
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Geographic Region; Blood and lymphatic system disorders, All (N=205)



Patients at risk					
Atezo, Asia Pacific and Australia	29	23	21	4	NE
Atezo, Europe and Middle East	65	53	47	5	1
Atezo, North America	10	8	7	2	NE
BSC, Asia Pacific and Australia	23	22	18	10	NE
BSC, Europe and Middle East	68	63	52	36	NE
BSC, North America	10	10	10	7	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21 JAN 2021

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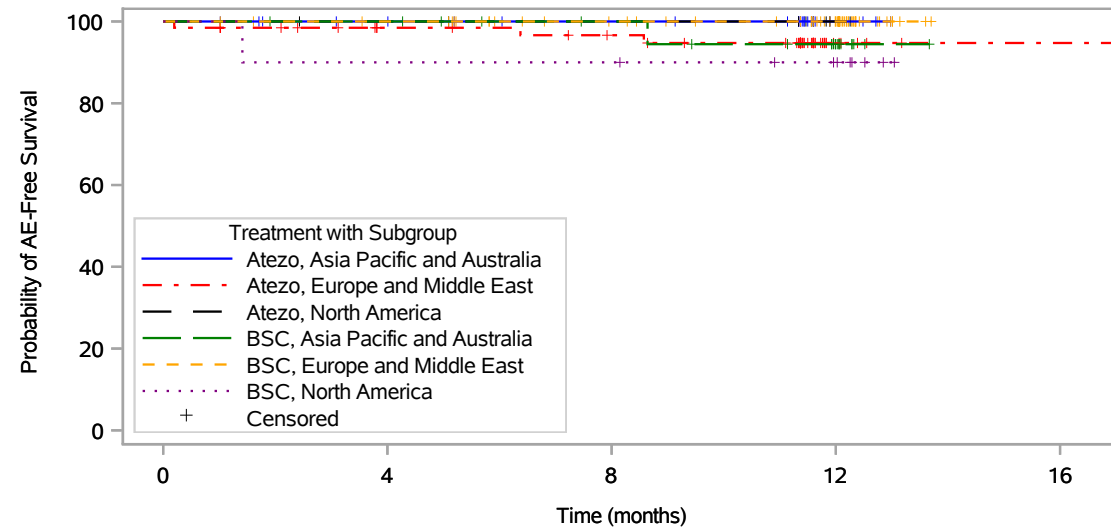
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Geographic Region; Reproductive system and breast disorders, All (N=205)



Patients at risk					
Atezo, Asia Pacific and Australia	29	25	22	4	NE
Atezo, Europe and Middle East	65	55	51	6	1
Atezo, North America	10	9	8	2	NE
BSC, Asia Pacific and Australia	23	22	18	10	NE
BSC, Europe and Middle East	68	65	55	38	NE
BSC, North America	10	9	9	6	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21 JAN 2021

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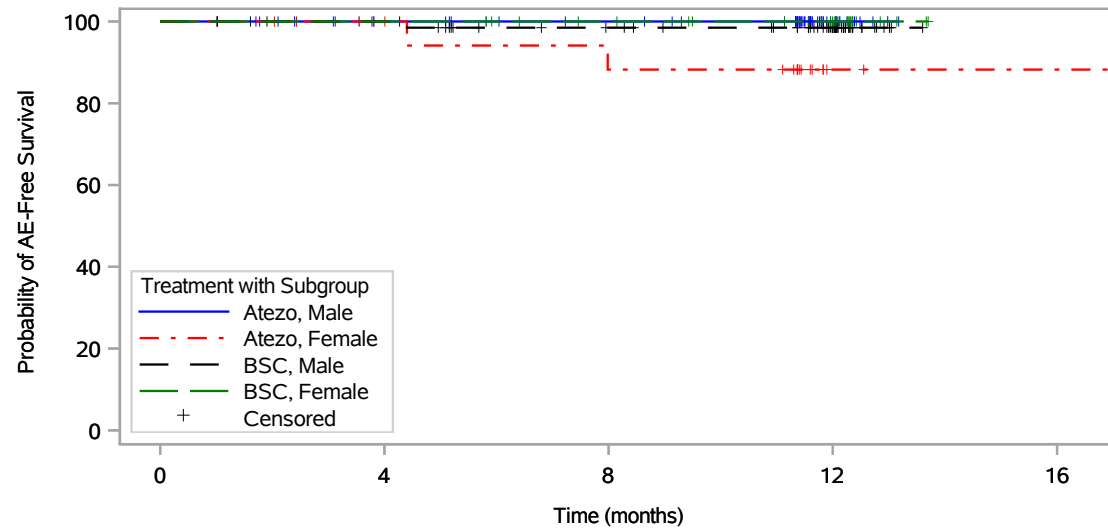
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Sex; Gastrointestinal disorders, Vomiting (N=205)



Patients at risk	0	4	8	12	16
Atezo, Male	82	71	66	11	NE
Atezo, Female	22	18	15	2	1
BSC, Male	71	67	57	37	NE
BSC, Female	30	30	25	17	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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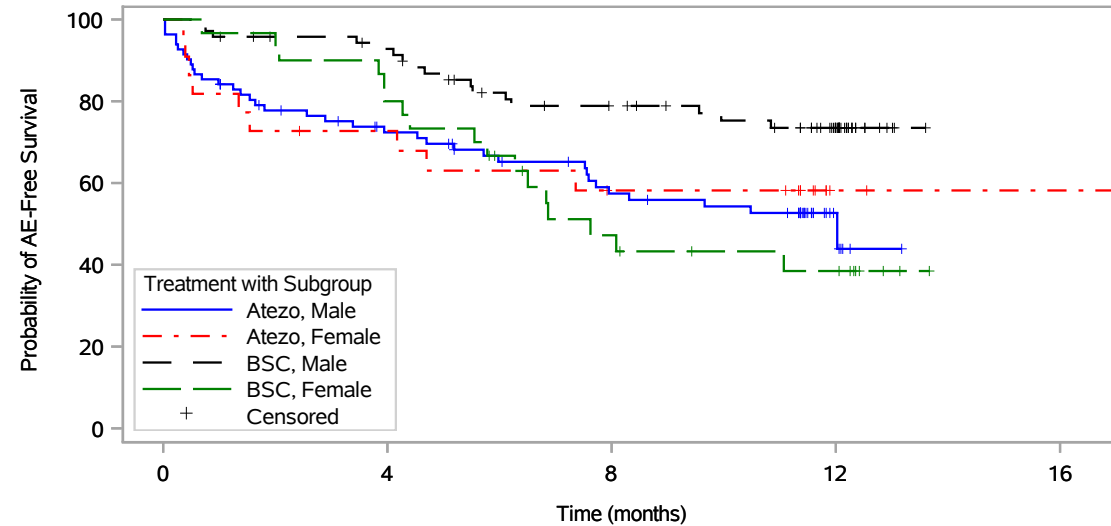
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Sex; Infections and infestations, All (N=205)



Patients at risk	0	4	8	12	16
Atezo, Male	82	52	37	6	NE
Atezo, Female	22	15	11	2	1
BSC, Male	71	62	47	28	NE
BSC, Female	30	24	12	8	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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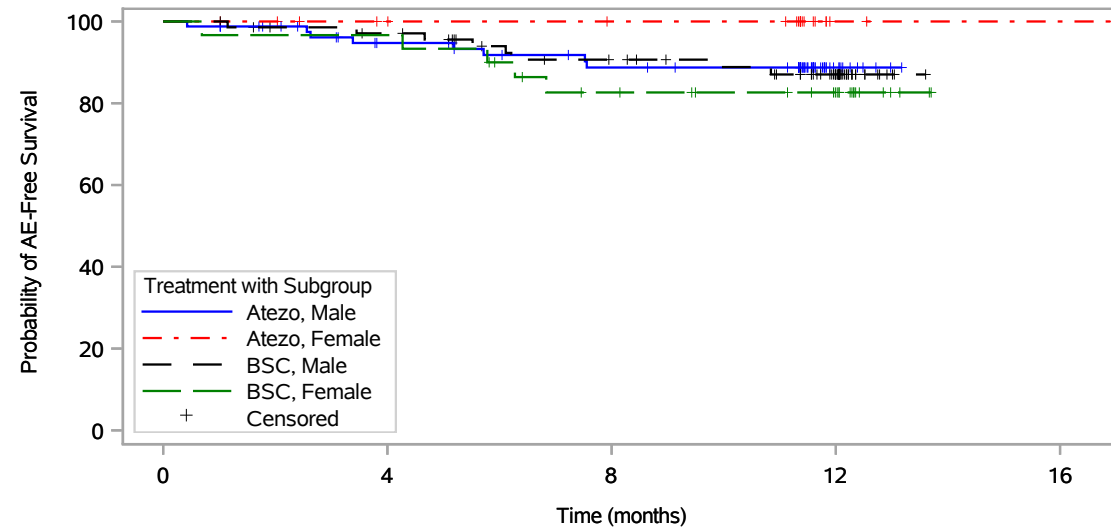
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Sex; Infections and infestations, Nasopharyngitis (N=205)



Patients at risk	0	4	8	12	16
Atezo, Male	82	67	58	10	NE
Atezo, Female	22	18	16	2	1
BSC, Male	71	65	53	33	NE
BSC, Female	30	29	21	14	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

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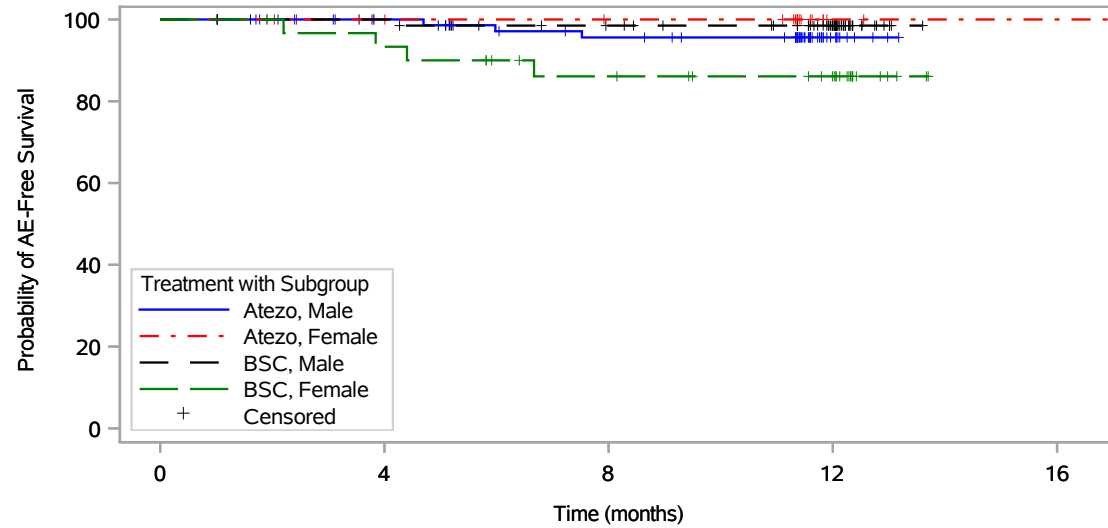
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Sex; Infections and infestations, Upper respiratory tract infection (N=205)



Patients at risk	0	4	8	12	16
Atezo, Male	82	71	63	10	NE
Atezo, Female	22	18	16	2	1
BSC, Male	71	67	57	37	NE
BSC, Female	30	28	22	16	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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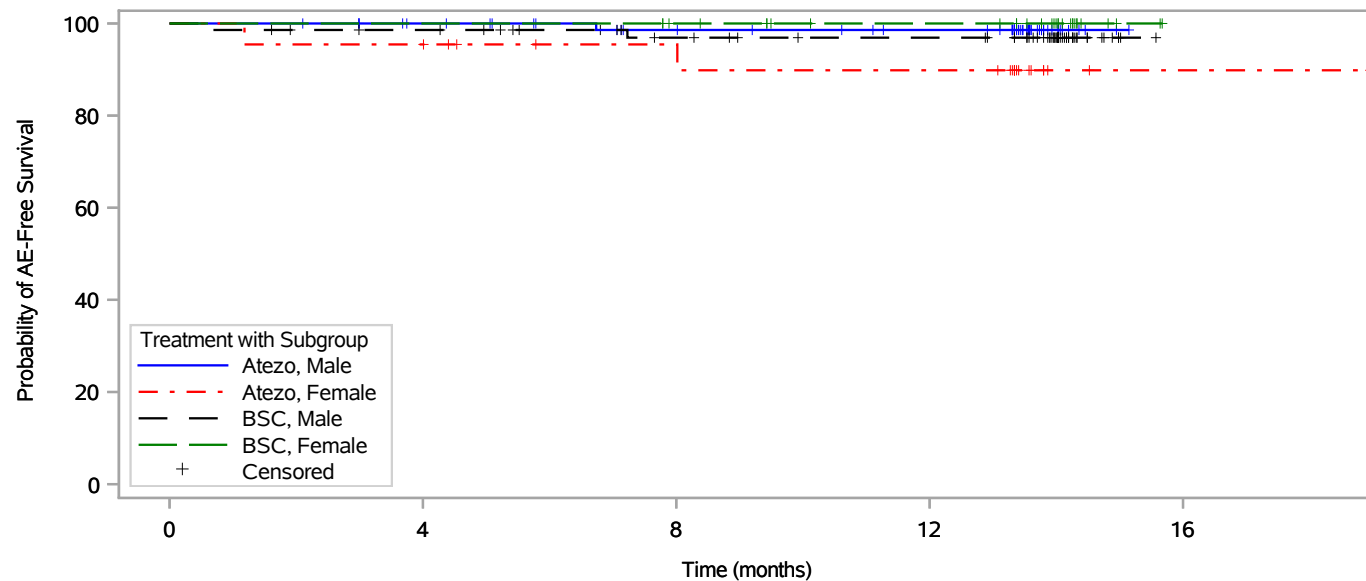
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

STUDY: GO29527

Sex; Nervous system disorders, All (N=205)



Patients at risk

Atezo, Male	82	76	67	62	NE
Atezo, Female	22	21	17	16	1
BSC, Male	71	67	57	53	NE
BSC, Female	30	30	27	22	NE

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21 JAN 2021

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Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Spezifische Verträglichkeit

Operationalisierung der Adverse Events of Special Interest (AESI)

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Rash	Sponsor defined AEGT	Atezo immune-mediate rash CURRENT AEGT consisting of the following PTs: Acne, Acne cystic, Acne fulminans, Acne pustular, Acquired epidermolysis bullosa, Administration site vesicles, Anal blister, Application site acne, Application site vesicles, Autoimmune blistering disease, Benign familial pemphigus, Blister, Blister rupture, Blood blister, Bullous erysipelas, Bullous haemorrhagic dermatosis, Bullous impetigo, Butterfly rash, Catheter site vesicles, Cervical bulla, Coma blister, Dermatitis, Dermatitis acneiform, Dermatitis allergic, Dermatitis herpetiformis, Dermatitis infected, Diabetic bullosis, Drug eruption, Eczema, Eczema infected, Eczema vesicular, Eczema weeping, Epidermal necrosis, Epidermolysis, Epidermolysis bullosa, Erythema, Erythema of eyelid, Eyelid folliculitis, Eyelid rash, Fixed eruption, Folliculitis, Fracture blisters, Furuncle, Genital blister, Hand dermatitis, Herpes gestationis, Immune-mediated dermatitis, Implant site vesicles, Incision site vesicles, Infusion site vesicles, Injection site vesicles, Instillation site vesicles, Linear IgA disease, Lip blister, Medical device site vesicles, Mucocutaneous rash, Mucosa vesicle, Nodular rash, Ocular pemphigoid, Oedema blister, Oral blood blister, Palmar-plantar erythrodysesthesia syndrome, Paraneoplastic pemphigus, Pemphigoid, Pemphigus, Penile blister, Porphyria non-acute, PRIDE syndrome, Pseudoporphyria, Pseudosyndactyly, Rash, Rash erythematous, Rash follicular, Rash macular, Rash maculo-papular, Rash maculovesicular, Rash morbilliform, Rash papular, Rash papulosquamous, Rash pruritic, Rash pustular, Rash rubelliform, Rash scarlatiniform, Rash vesicular, Scrotal dermatitis, Seborrheic dermatitis, Skin exfoliation, Skin toxicity, Skin ulcer, Staphylococcal scalded skin syndrome, Symmetrical drug-related intertriginous and flexural exanthema, Toxic erythema of chemotherapy, Urticarial dermatitis, Vaccination site vesicles, Vascular access site rash, Vascular access site vesicles, Vasculitic rash, Vessel puncture site vesicles, Vulvovaginal exfoliation
Immune-Mediated Hepatitis	SMQ	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) narrow
	SMQ	Hepatitis, non-infectious (SMQ) narrow
	SMQ	Liver related investigations, signs and symptoms (SMQ) narrow
Immune-Mediated Hypothyroidism	SMQ	Hypothyroidism (SMQ) wide
Immune-Mediated Hyperthyroidism	SMQ	Hyperthyroidism (SMQ) narrow
Immune-Mediated Pneumonitis	SMQ	Interstitial lung disease (SMQ) narrow
Immune-Mediated Severe Cutaneous Reaction	SMQ	Severe cutaneous adverse reactions (SMQ) narrow
Immune-Mediated Meningoencephalitis	SMQ	Noninfectious meningitis (SMQ) narrow
	SMQ	Noninfectious encephalitis (SMQ) narrow
Immune-Mediated Meningitis	SMQ	Noninfectious meningitis (SMQ) narrow
Immune-Mediated Encephalitis	SMQ	Noninfectious encephalitis (SMQ) narrow
Immune-Mediated Colitis	HLT	Colitis (excl infective)

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Guillain-Barre	SMQ	Guillain-Barre syndrome (SMQ) narrow
Immune-Mediated Ocular Inflammatory Toxicity	Sponsor defined AEGT	Atezolizumab Ocular Inflammation Toxicity AEGT consisting of the following PTs: Anterior chamber inflammation, Atopic keratoconjunctivitis, Autoimmune eye disorder, Autoimmune retinopathy, Autoimmune uveitis, Chorioretinitis, Chorioretinopathy, Choroidal detachment, Choroiditis, Corneal endotheliitis, Detachment of macular retinal pigment epithelium, Detachment of retinal pigment epithelium, Diffuse lamellar keratitis, Episcleritis, Eye inflammation, Immune recovery uveitis, Immune-mediated uveitis, Iridocyclitis, Iritis, Keratitis, Keratitis interstitial, Necrotising retinitis, Necrotising scleritis, Non-infectious endophthalmitis, Noninfective chorioretinitis, Noninfective conjunctivitis, Noninfective retinitis, Ocular pemphigoid, Ocular vasculitis, Optic neuritis, Optic neuropathy, Optic perineuritis, Papillitis, Punctate keratitis, Retinal detachment, Retinal vasculitis, Retinitis, Retinopathy, Retinoschisis, Rheumatoid scleritis, Scleritis, Serpiginous choroiditis, Superior limbic keratoconjunctivitis, Ulcerative keratitis, Uveitis, Vitritis
Autoimmune Hemolytic Anaemia	SMQ	Haemolytic disorders (SMQ) narrow
Immune-Mediated Adrenal Insufficiency	Sponsor defined AEGT	Atezolizumab comprehensive adrenal insufficiency search AEGT consisting of the following PTs: ACTH stimulation test abnormal, Addison's disease, Adrenal androgen deficiency, Adrenal atrophy, Adrenal insufficiency, Adrenal insufficiency neonatal, Adrenal suppression, Adrenalitis, Adrenocortical insufficiency acute, Adrenocortical insufficiency neonatal, Adrenocorticotrophic hormone deficiency, Adrenogenital syndrome, Aldosterone urine abnormal, Aldosterone urine decreased, Apituitarism, Biopsy adrenal gland abnormal, Blood aldosterone abnormal, Blood aldosterone decreased, Blood corticosterone abnormal, Blood corticosterone decreased, Blood corticotrophin abnormal, Blood corticotrophin decreased, Blood corticotrophin increased, Corticotropin-releasing hormone stimulation test, Cortisol decreased, Cortisol free urine decreased, Dexamethasone suppression test, Dexamethasone suppression test positive, Glucocorticoid deficiency, Glucocorticoids abnormal, Glucocorticoids decreased, Hydroxycorticosteroids urine abnormal, Hydroxycorticosteroids urine decreased, Hypoaldosteronism, Hypothalamic pituitary adrenal axis suppression, Mineralocorticoid deficiency, Primary adrenal insufficiency, Scan adrenal gland abnormal, Secondary adrenocortical insufficiency, Steroid withdrawal syndrome, Triple A syndrome, Urine cortisol/creatinine ratio abnormal, Urine cortisol/creatinine ratio decreased
Immune-Mediated Diabetes Mellitus	Sponsor defined AEGT	Atezolizumab Diabetes/DKA (excludes hyperglycemia) AEGT consisting of the following MedDRA PTs: Diabetes mellitus, Diabetic coma, Diabetic hyperglycaemic coma, Diabetic ketoacidosis, Diabetic ketoacidotic hyperglycaemic coma, Fulminant type 1 diabetes mellitus, Ketoacidosis, Latent autoimmune diabetes in adults, Type 1 diabetes mellitus
Immune-Mediated Hypophysitis	HLT	Hypothalamic and pituitary disorders NEC
Immune-Mediated Myasthenia Gravis	HLT	Myasthenia gravis and related conditions
Immune-Mediated Myocarditis	Sponsor defined AEGT	Atezolizumab Myocarditis Immune-Mediated AEGT consisting of the following PTs: Autoimmune myocarditis, Eosinophilic myocarditis, Giant cell myocarditis, Hypersensitivity myocarditis, Immune-mediated myocarditis, Myocarditis

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Myositis	HLT	Muscle infections and inflammations
	HLT	Muscular autoimmune disorders
Immune-Mediated Nephritis	HLT	Glomerulonephritis and nephrotic syndrome
	HLT	Nephritis NEC
Immune-Mediated Pancreatitis	Sponsor defined AEGT	Atezolizumab pancreatitis AEGT consisting of the the following MedDRA PTs: Amylase abnormal, Amylase increased, Autoimmune pancreatitis, Cullen's sign, Grey Turner's sign, Haemorrhagic necrotic pancreatitis, Hereditary pancreatitis, Ischaemic pancreatitis, Lipase abnormal, Lipase increased, Oedematous pancreatitis, Pancreatic abscess, Pancreatic enzyme abnormality, Pancreatic enzymes abnormal, Pancreatic enzymes increased, Pancreatic haemorrhage, Pancreatic necrosis, Pancreatic phlegmon, Pancreatic pseudocyst, Pancreatic pseudocyst drainage, Pancreatitis, Pancreatitis acute, Pancreatitis haemorrhagic, Pancreatitis necrotising, Pancreatitis relapsing, Pancreatorenal syndrome, Subacute pancreatitis
Immune-Mediated Vasculitis	SMQ	Vasculitis (SMQ) narrow
Infusion-Related Reaction	PT	Infusion Related Reaction (Only include if occurred on same day or within 1 day of atezolizumab infusion)
	PT	Cytokine release syndrome (Only include if occurred on same day or within 1 day of atezolizumab infusion)
Rhabdomyolysis	SMQ	Rhabdomyolysis/myopathy (SMQ) narrow

AEGT = Adverse Event Group Term; AESI = adverse event of special interest; EGFR = epidermal growth factor receptor; HLT = High Level Term; MedDRA = Medical Dictionary for Regulatory Activities; NEC = not elsewhere classified; PT = Preferred Term; SMQ = Standardized MedDRA Query.

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Spezifische Verträglichkeit

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	19	18,3	85	81,7	101	100,0	1	1,0	100	99,0	<.0001	20,54	2,75	153,44	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	14	17,1	68	82,9	71	70,3	1	1,4	70	98,6	0,0012	13,19	1,73	100,32	Convergence criterion (GCONV=1E-8) satisfied.	0,3359
	Female	22	21,2	5	22,7	17	77,3	30	29,7	0	0,0	30	100,0	0,0060	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	9	14,1	55	85,9	62	61,4	0	0,0	62	100,0	0,0020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2781
	>= 65	40	38,5	10	25,0	30	75,0	39	38,6	1	2,6	38	97,4	0,0039	11,10	1,42	86,73	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	0	0,0	23	100,0	0,0215	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4943

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	1	1,5	67	98,5	0,0071	9,95	1,26	78,58	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0201	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	6	19,4	25	80,6	33	32,7	0	0,0	33	100,0	0,0080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5940
	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	10	21,7	36	78,3	53	52,5	1	1,9	52	98,1	0,0015	13,09	1,67	102,32	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMRH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
28FEB2022 11:20

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMRH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMRHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 11:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	14	13,5	90	86,5	101	100,0	5	5,0	96	95,0	0,0342	2,87	1,03	7,97	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	12	14,6	70	85,4	71	70,3	4	5,6	67	94,4	0,0703	2,73	0,88	8,46	Convergence criterion (GCONV=1E-8) satisfied.	0,9572
	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,4086	2,65	0,24	29,19	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	10	15,6	54	84,4	62	61,4	5	8,1	57	91,9	0,1728	2,08	0,71	6,08	Convergence criterion (GCONV=1E-8) satisfied.	0,0972
	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0461	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	2	8,7	21	91,3	0,2126	2,67	0,54	13,29	Convergence criterion (GCONV=1E-8) satisfied.	0,7029

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	3	4,4	65	95,6	0,1695	2,50	0,65	9,66	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	3	9,7	28	90,3	33	32,7	5	15,2	28	84,8	0,5096	0,62	0,15	2,60	Convergence criterion (GCONV=1E-8) satisfied.	0,0024
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	9	19,6	37	80,4	53	52,5	0	0,0	53	100,0	0,0007	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHP_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
25FEB2022 18:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis Grade \geq 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0	101	100,0	0,0255	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0	71	100,0	0,0616	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0	62	100,0	0,0836	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	\geq 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1595	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0	23	100,0	0,2002	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0	68	100,0	0,0767	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0	53	100,0	0,0139	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHP35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 25FEB2022 18:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3066	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,2884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHPS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:32

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	16	15,4	88	84,6	101	100,0	0	0	101	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	15	18,3	67	81,7	71	70,3	0	0	71	100,0	0,0002	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	10	15,6	54	84,4	62	61,4	0	0	62	100,0	0,0011	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	0	0	39	100,0	0,0111	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0	23	100,0	0,1175	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	0	0	68	100,0	0,0004	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0	10	100,0	0,1464	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	6	19,4	25	80,6	33	32,7	0	0	33	100,0	0,0072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	6	22,2	21	77,8	15	14,9	0	0	15	100,0	0,0533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0	53	100,0	0,0273	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMLT_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:36

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMLT35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:39

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMLTS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:43

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2556	2,51	0,49	12,94	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2338	3,49	0,39	31,28	Convergence criterion (GCONV=1E-8) satisfied.	0,6208
	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7851	1,47	0,09	23,50	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0975	5,11	0,60	43,80	Convergence criterion (GCONV=1E-8) satisfied.	0,0798
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6916	1,62	0,14	18,18	Convergence criterion (GCONV=1E-8) satisfied.	0,9265

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2893	3,18	0,33	30,62	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9069	1,12	0,16	7,99	Convergence criterion (GCONV=1E-8) satisfied.	0,2232
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0589	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHT_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHT35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:50

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMHTS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	6	5,8	98	94,2	101	100,0	0	0	101	100,0	0,0149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0	71	100,0	0,0361	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0	62	100,0	0,0808	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0	39	100,0	0,0846	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	0	0	23	100,0	0,0664	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0	33	100,0	0,0700	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0	53	100,0	0,0622	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMP_N_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 25FEB2022 19:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMP35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1635	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0	71	100,0	0,1886	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1627	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMPNS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1571	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0	71	100,0	0,1831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1542	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMSR_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMSR35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:33

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMSRS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:37

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMME_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:00

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMME35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:04

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMES_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMI_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMI35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMIS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMEF_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:38

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 28FEB2022 16:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMEFS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3794	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:17

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3794	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMCL35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 25FEB2022 19:24

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMGB_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMGB35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMGBS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3117	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3516	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3634	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMOT35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:51

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:54

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Autoimmune Hemolytic Anemia
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTAHA_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMAI_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 18:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Diabetes mellitus
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMDM_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypophysitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMLH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMG_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

25FEB2022 19:37

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myocarditis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMC_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 17:19

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myositis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMMY_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Nephritis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMNP_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 11:10

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pancreatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMPC_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Vasculitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIMVS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 16:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Infusion-Related Reactions
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Rhabdomyolysis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_tte_sg_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

28FEB2022 10:59

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

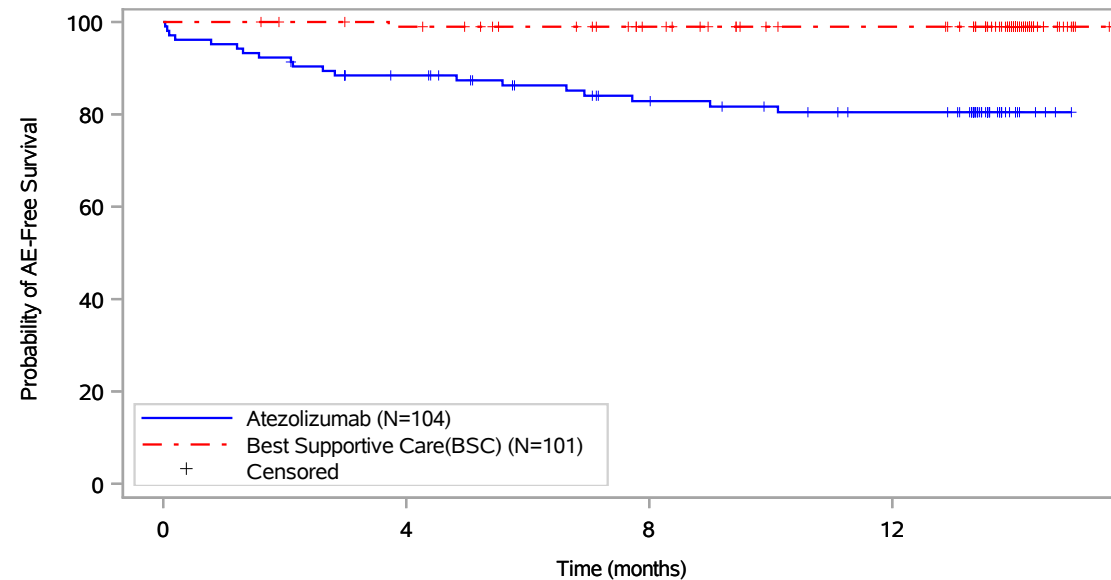
Spezifische Verträglichkeit

KM Plots

Unstratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash
STUDY: GO29527



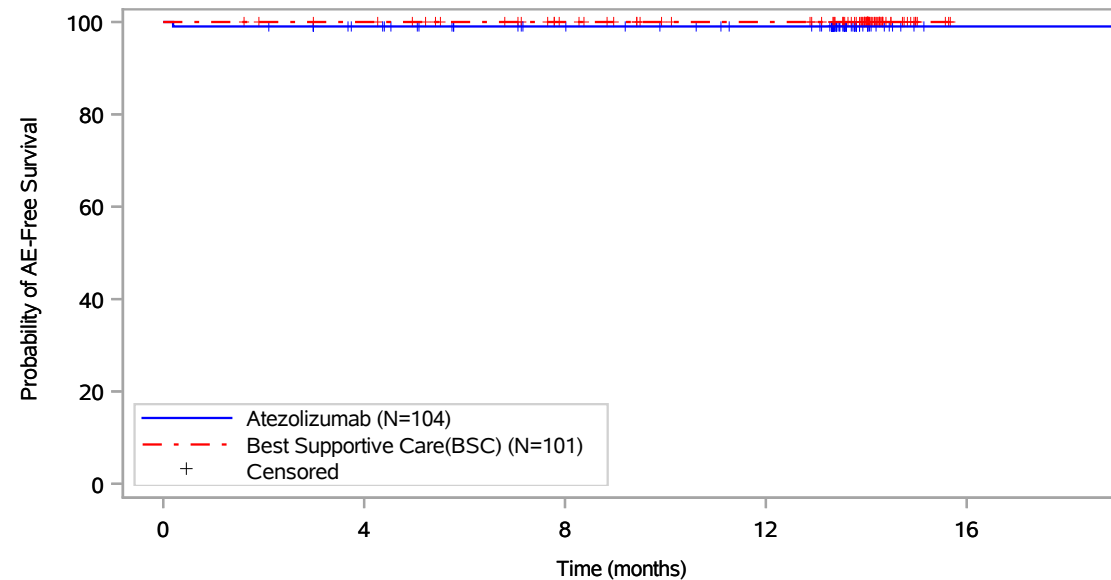
Patients at risk				
	0	4	8	12
Atezolizumab (N=104)	104	86	71	63
Best Supportive Care(BSC) (N=101)	101	97	85	76
Patients censored				
Atezolizumab (N=104)	0	6	16	22
Best Supportive Care(BSC) (N=101)	0	3	15	24

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIIMRH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 22:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash Grade \geq 3
STUDY: GO29527



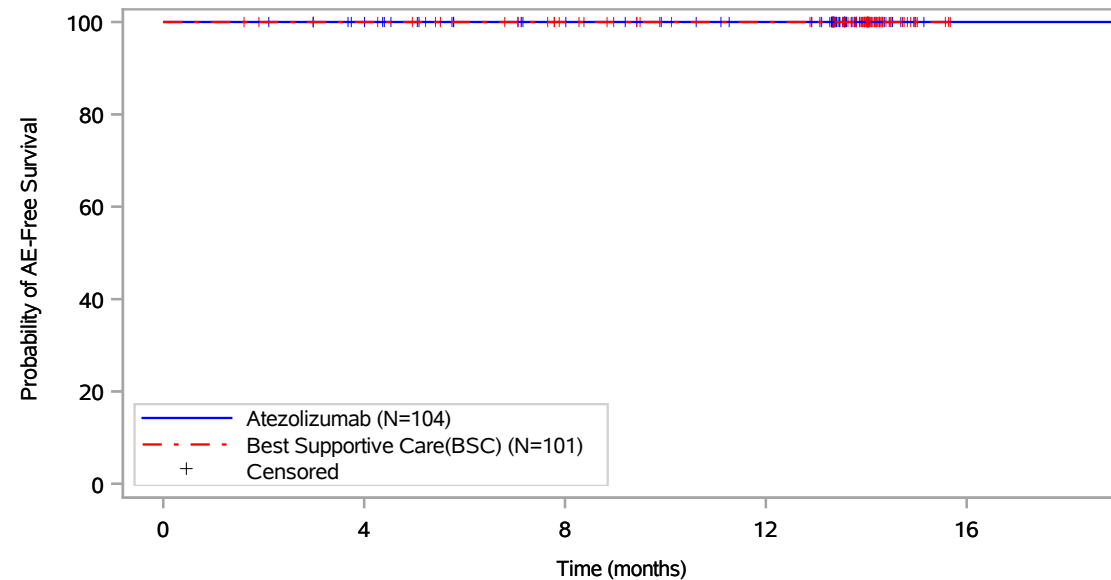
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 22:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash Serious
STUDY: GO29527



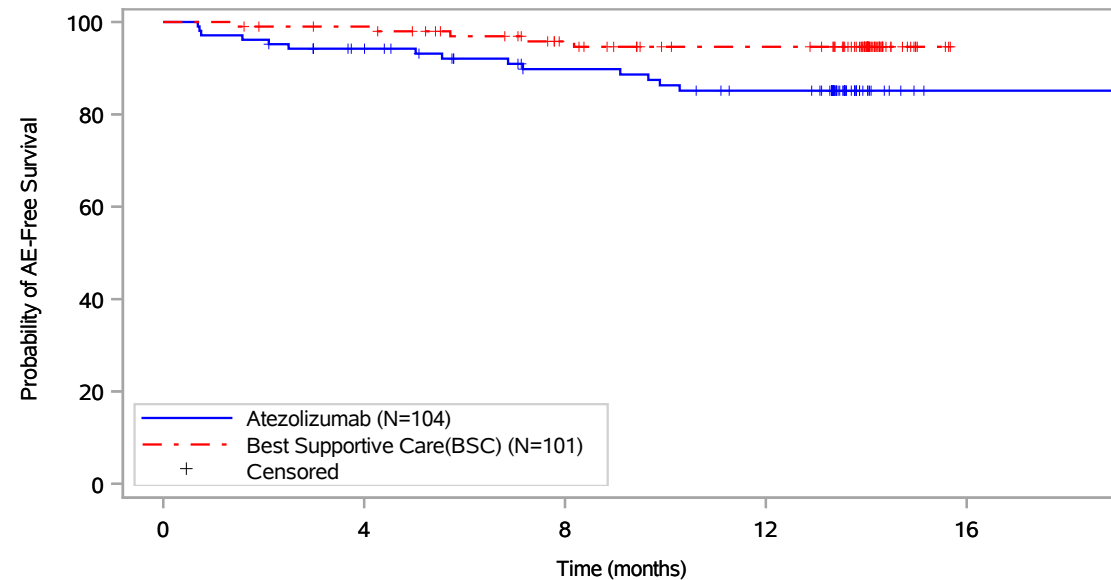
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 22:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis
STUDY: GO29527



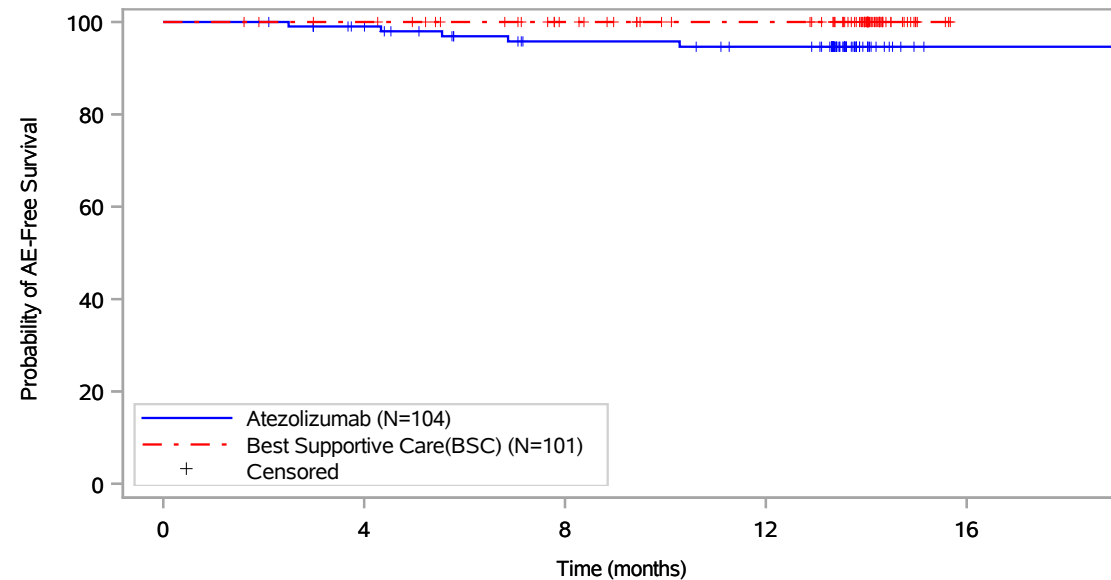
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	91	77	70	1
Best Supportive Care(BSC) (N=101)	101	97	82	72	NE
Patients censored					
Atezolizumab (N=104)	0	7	17	20	89
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MHP_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 18:51

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis Grade \geq 3
STUDY: GO29527



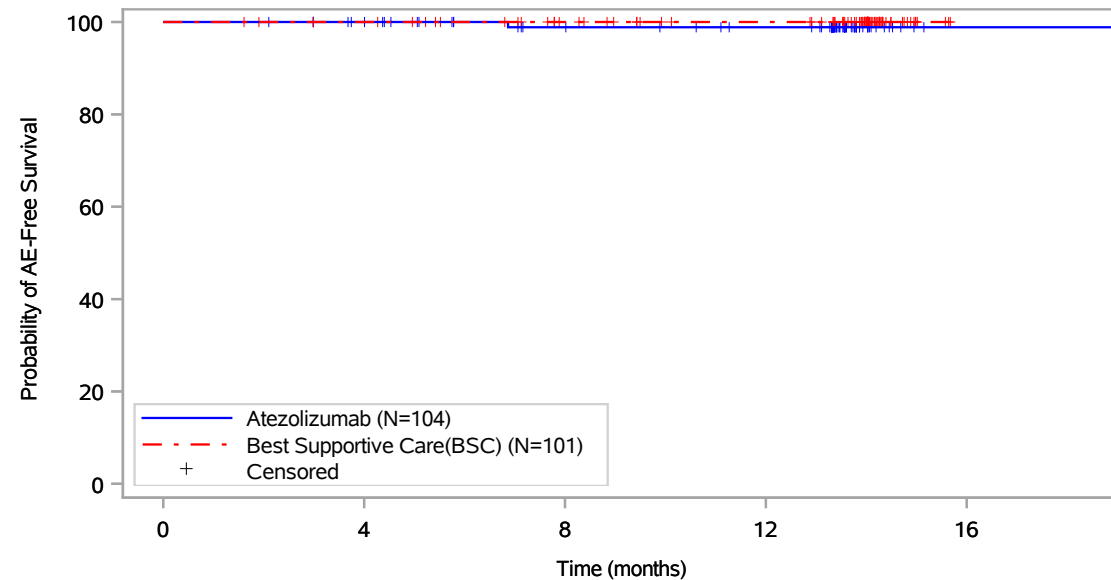
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	83	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	17	20	98
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 18:54

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis Serious
STUDY: GO29527



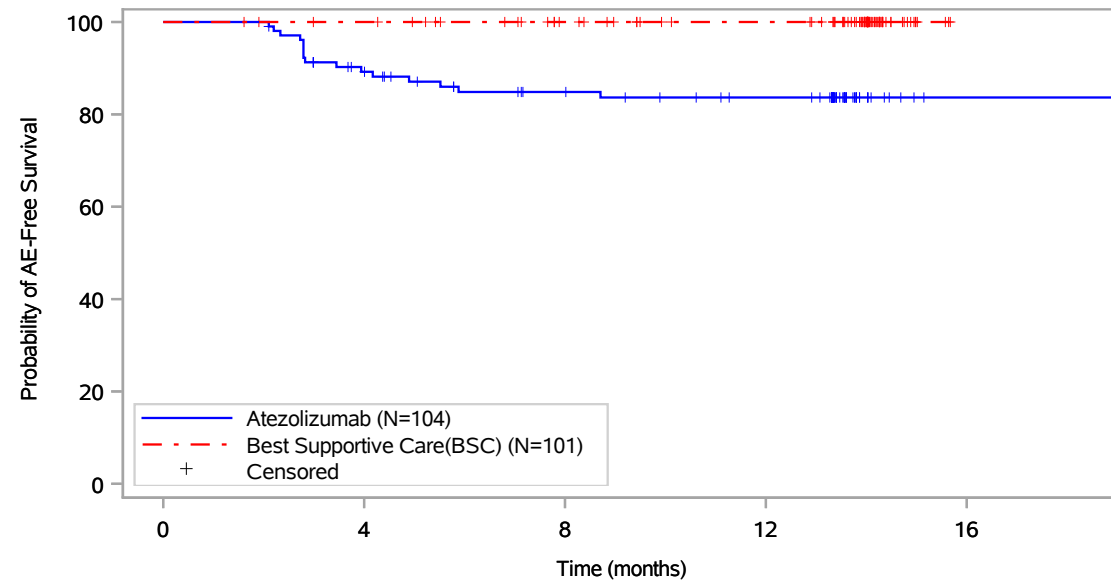
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 18:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism
STUDY: GO29527



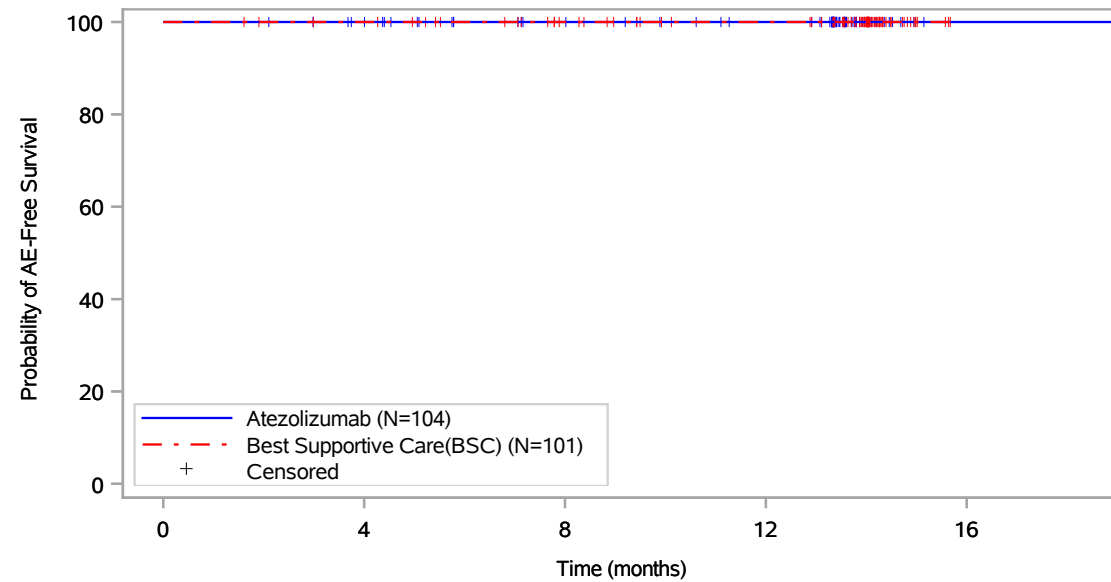
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	86	72	65	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	17	23	87
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:00

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism Grade \geq 3
STUDY: GO29527



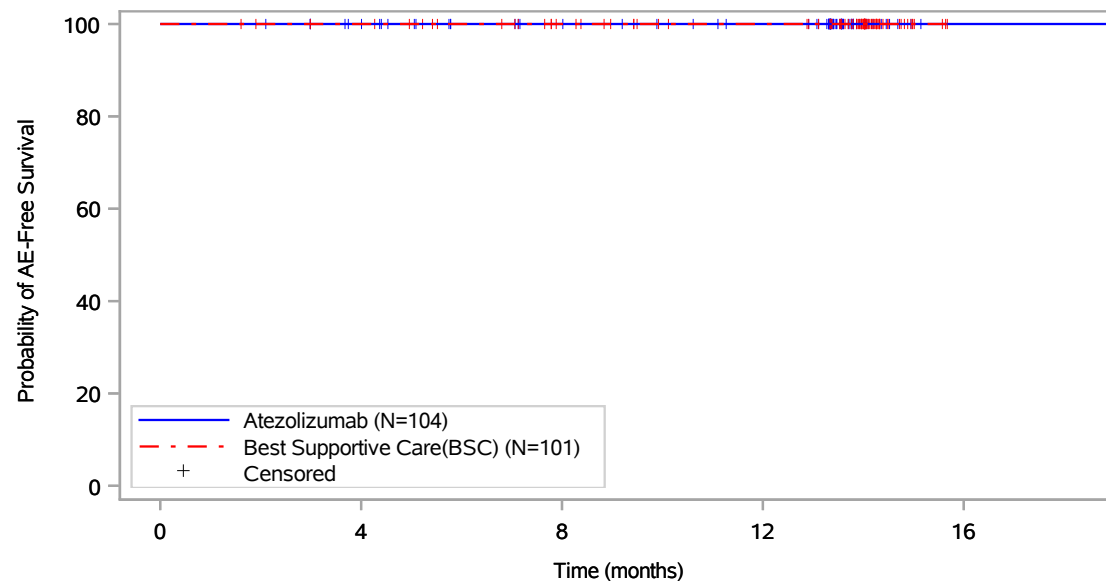
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:03

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism Serious
STUDY: GO29527



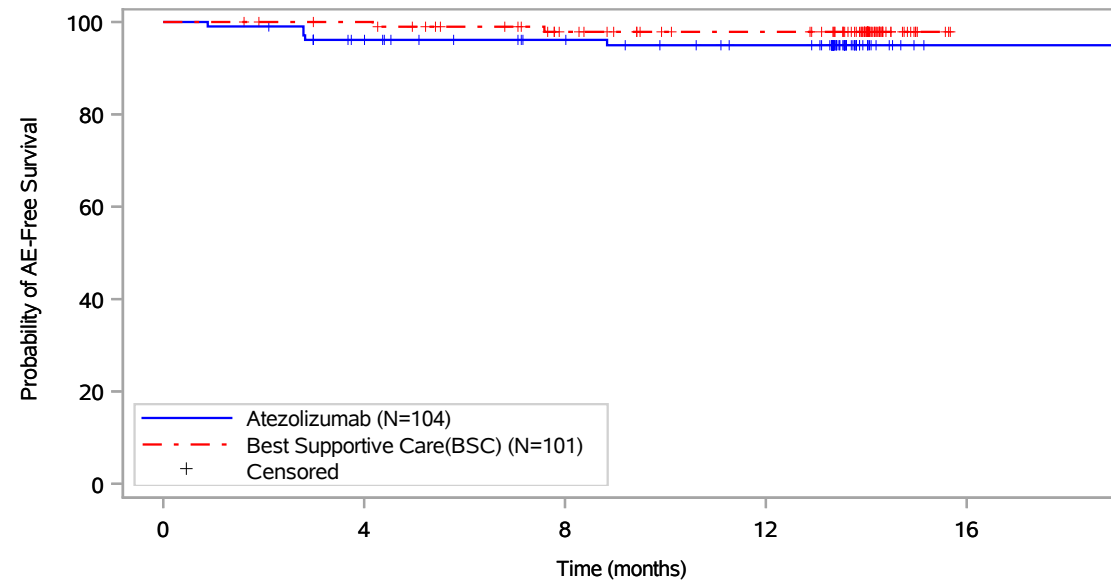
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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 13DEC2021 19:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism
STUDY: GO29527



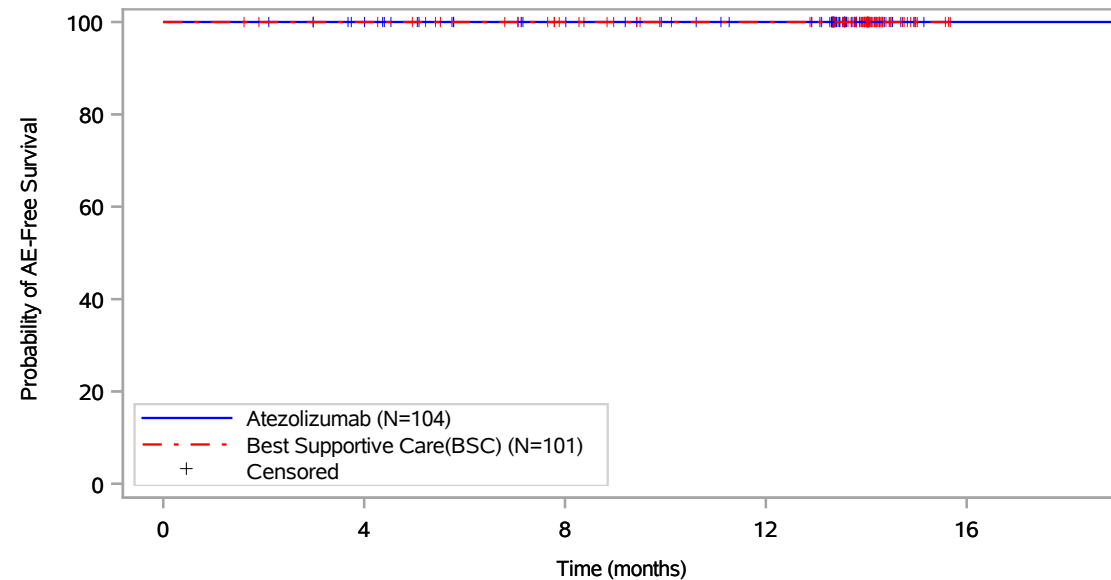
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	93	84	77	1
Best Supportive Care(BSC) (N=101)	101	98	84	75	NE
Patients censored					
Atezolizumab (N=104)	0	7	16	22	98
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Grade \geq 3
STUDY: GO29527



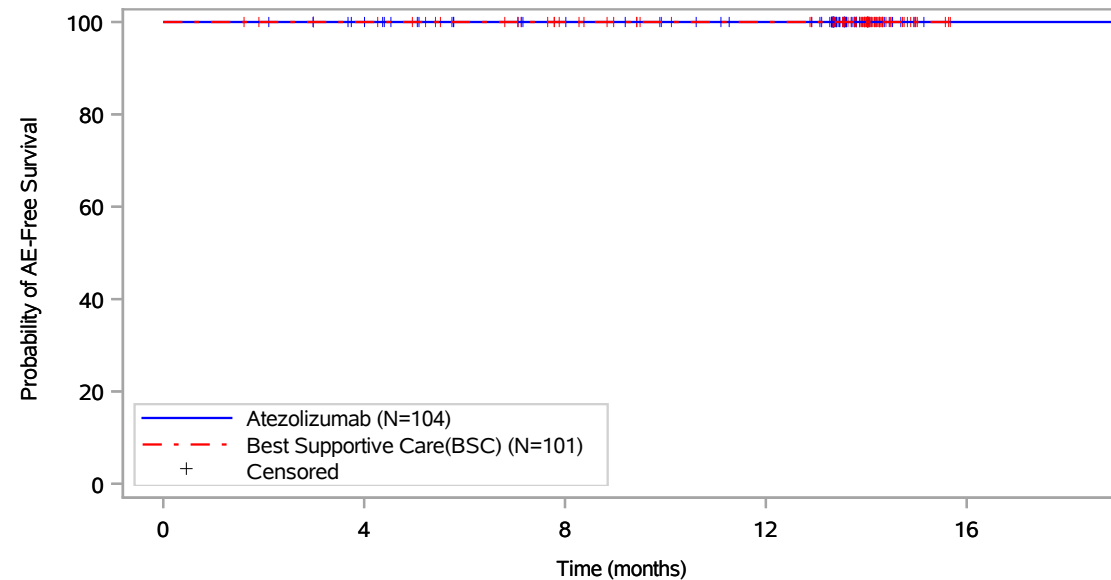
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Serious
STUDY: GO29527



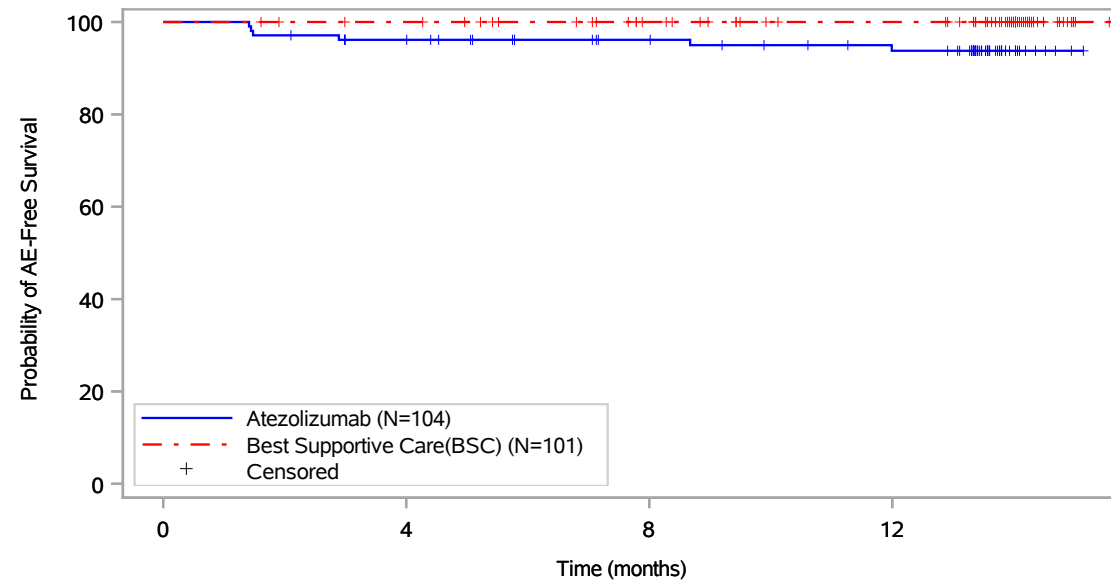
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

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 13DEC2021 19:15

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis
STUDY: GO29527



Patients at risk

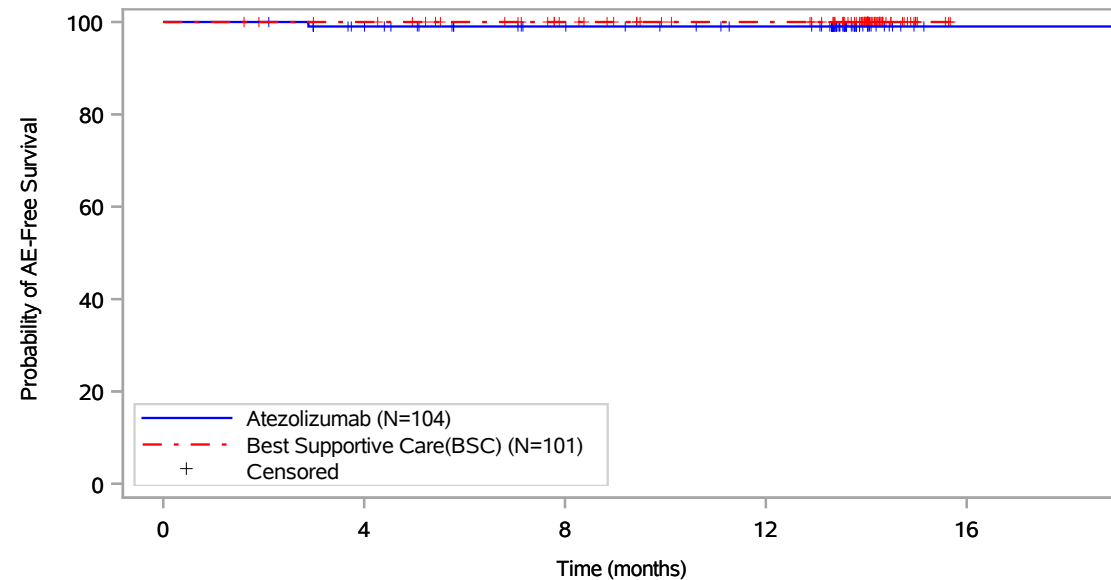
Atezolizumab (N=104)	104	95	84	77
Best Supportive Care(BSC) (N=101)	101	98	86	77
Patients censored				
Atezolizumab (N=104)	0	5	16	21
Best Supportive Care(BSC) (N=101)	0	3	15	24

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:26

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis Grade \geq 3
STUDY: GO29527



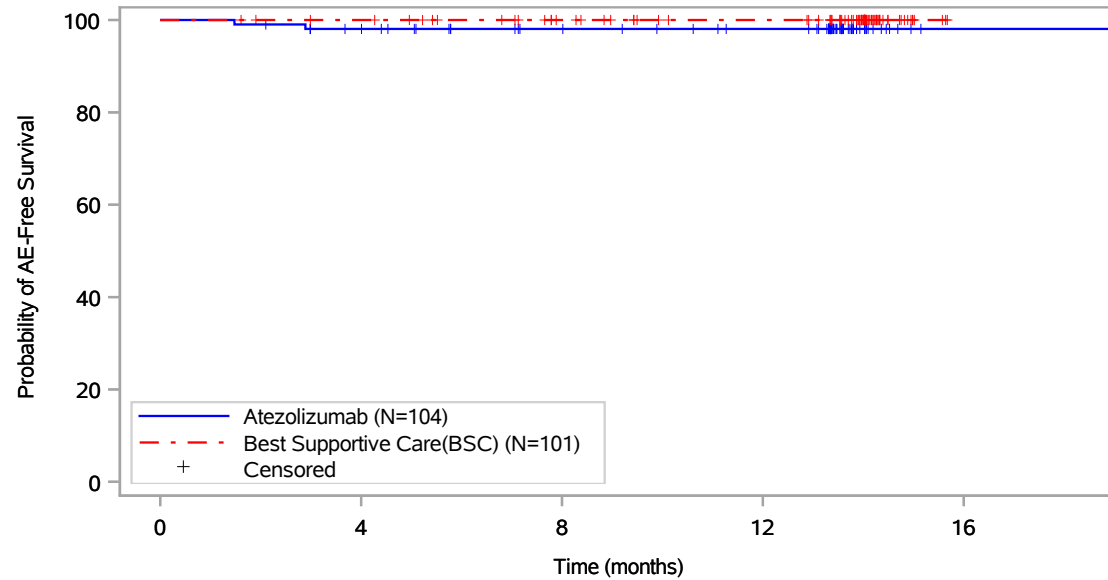
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis Serious
STUDY: GO29527



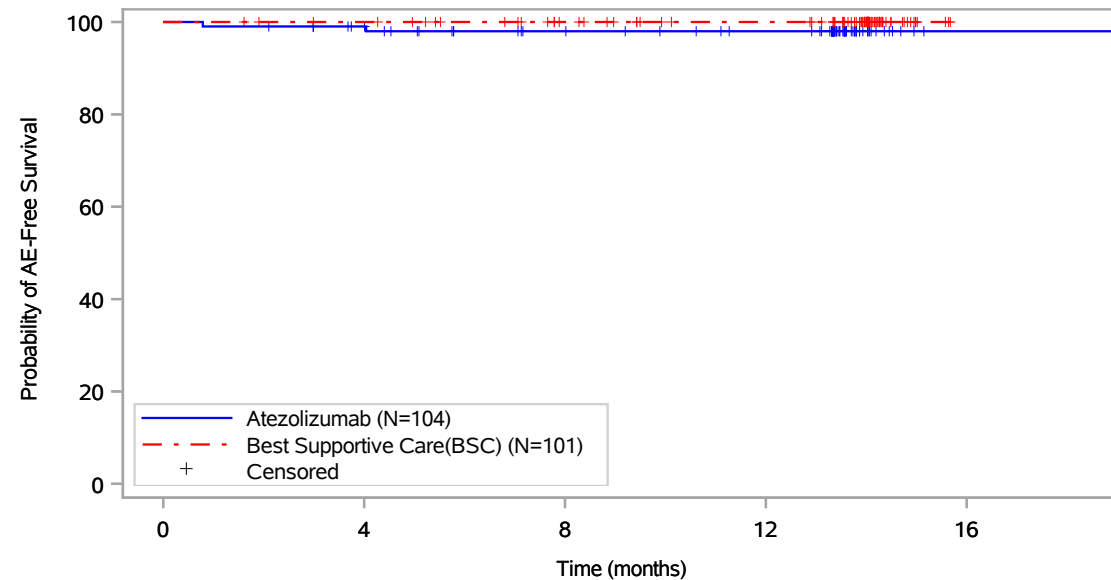
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 19:33

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions
STUDY: GO29527



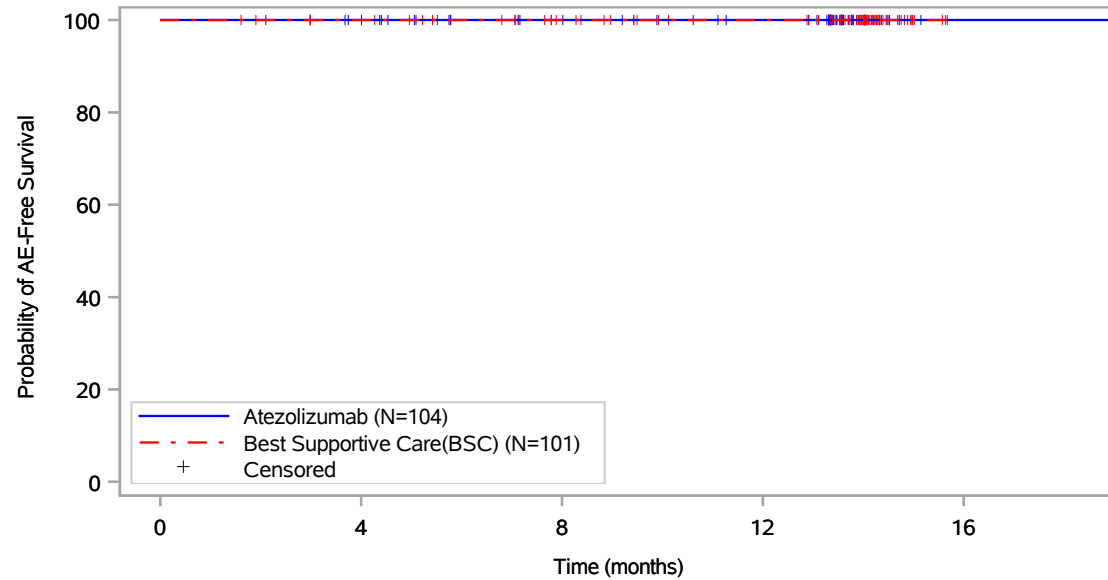
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 22:00

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Grade \geq 3
STUDY: GO29527



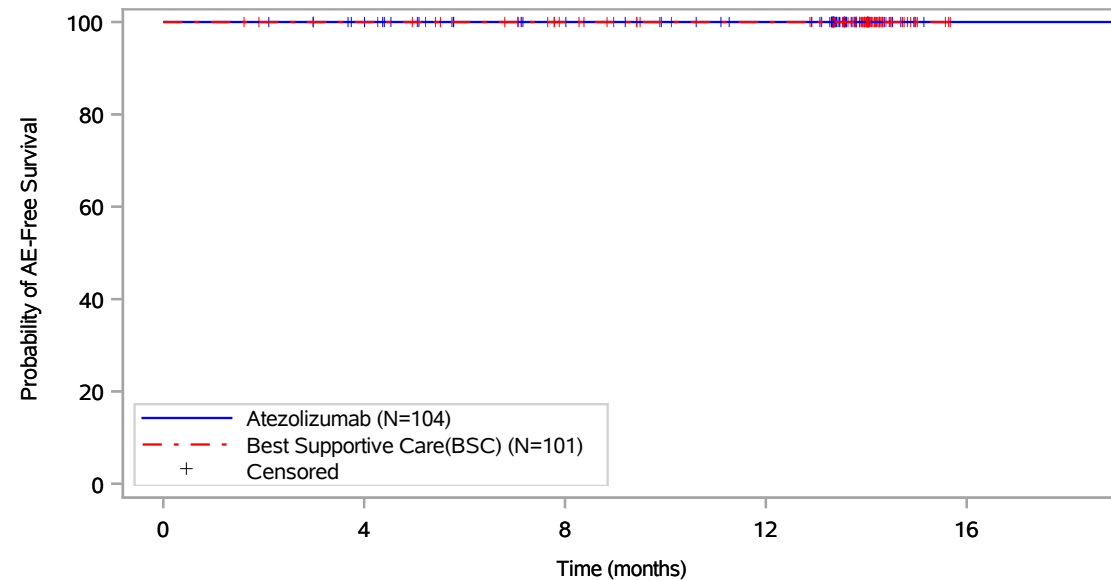
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 13DEC2021 22:03

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Serious
STUDY: GO29527



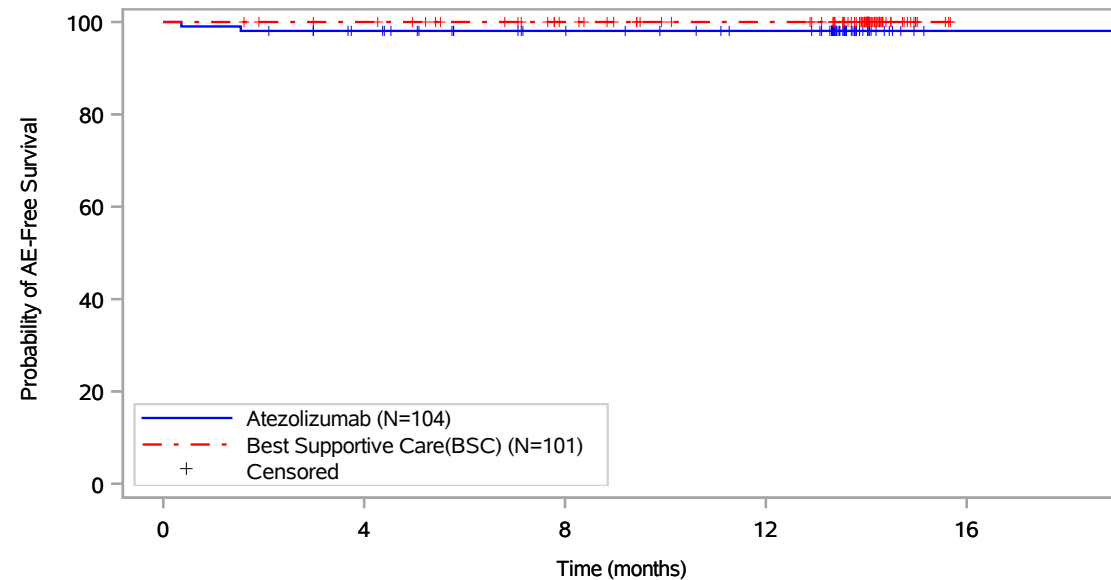
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMSRS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 22:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis
STUDY: GO29527



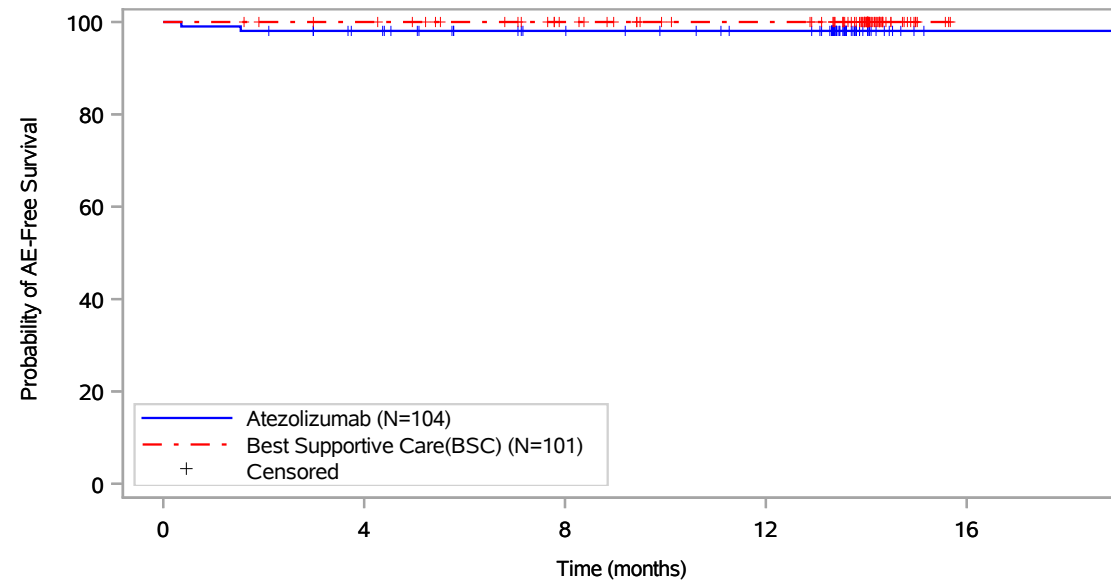
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIIME_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Grade \geq 3
STUDY: GO29527



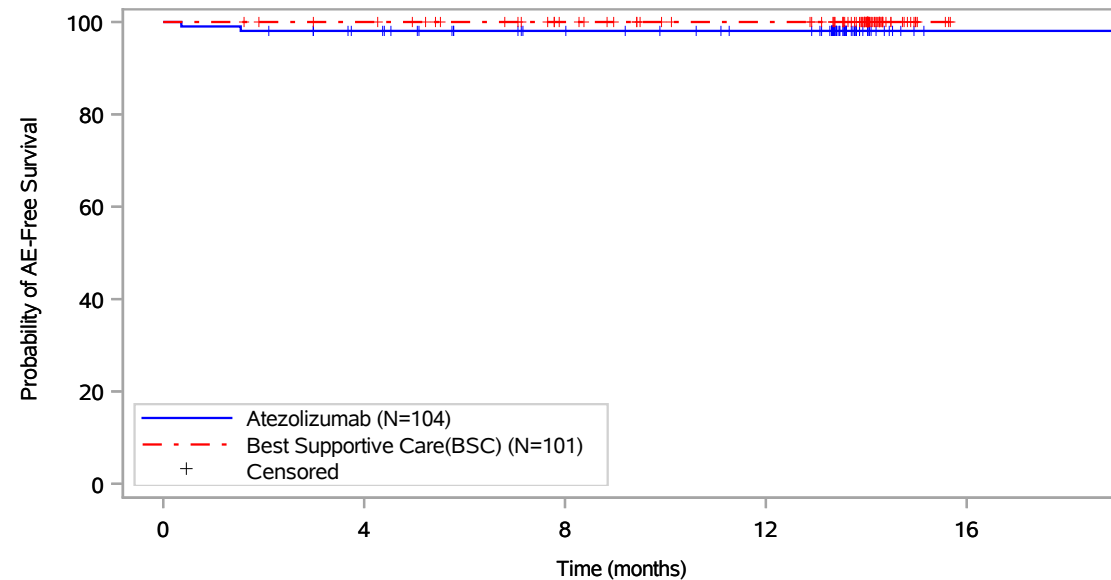
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..CE_DFS_IA/prod/output/g_km_TTIMME35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Serious
STUDY: GO29527



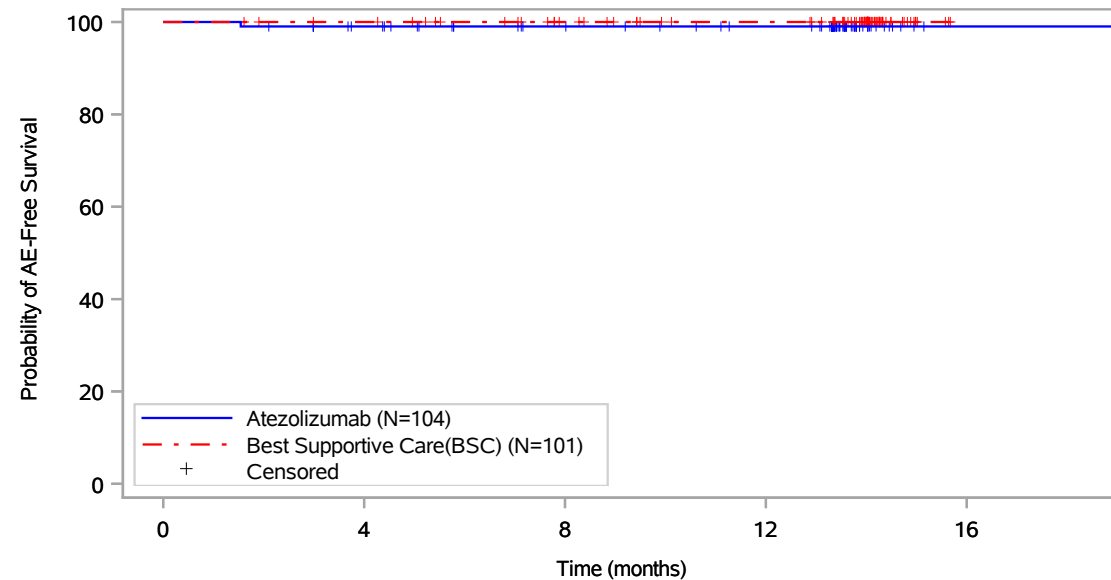
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	17	23	101
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMMES_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis
STUDY: GO29527



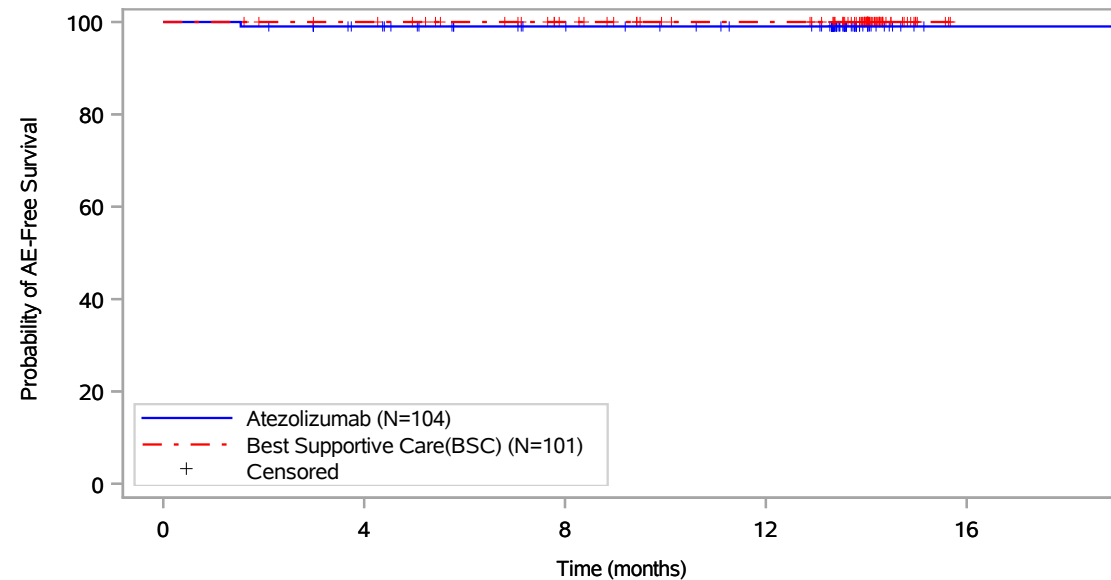
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIMMI_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis Grade \geq 3
STUDY: GO29527



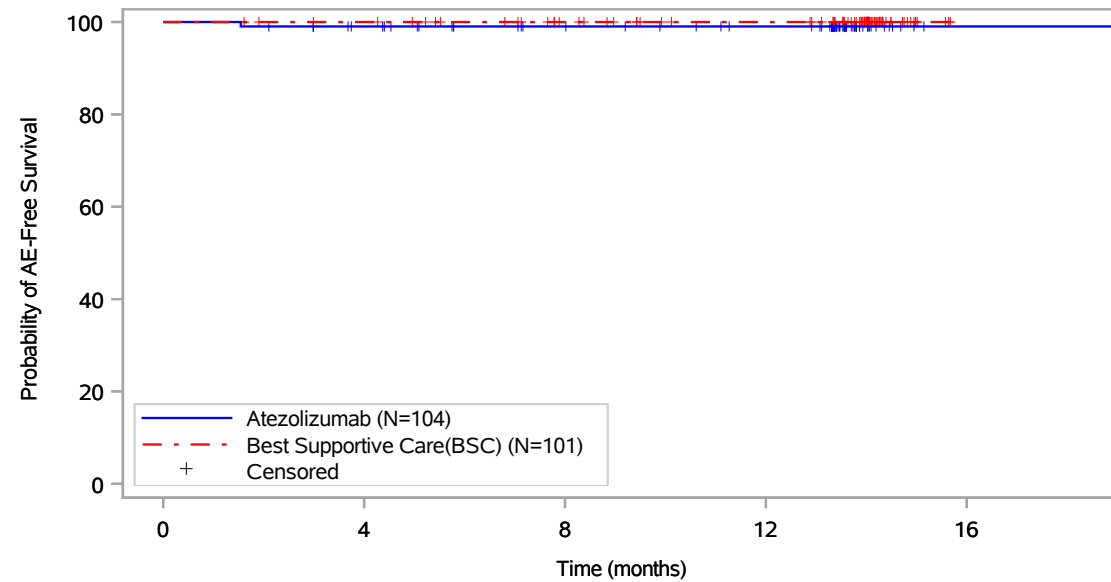
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...CE_DFS_IA/prod/output/g_km_TTIIMMI35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis Serious
STUDY: GO29527



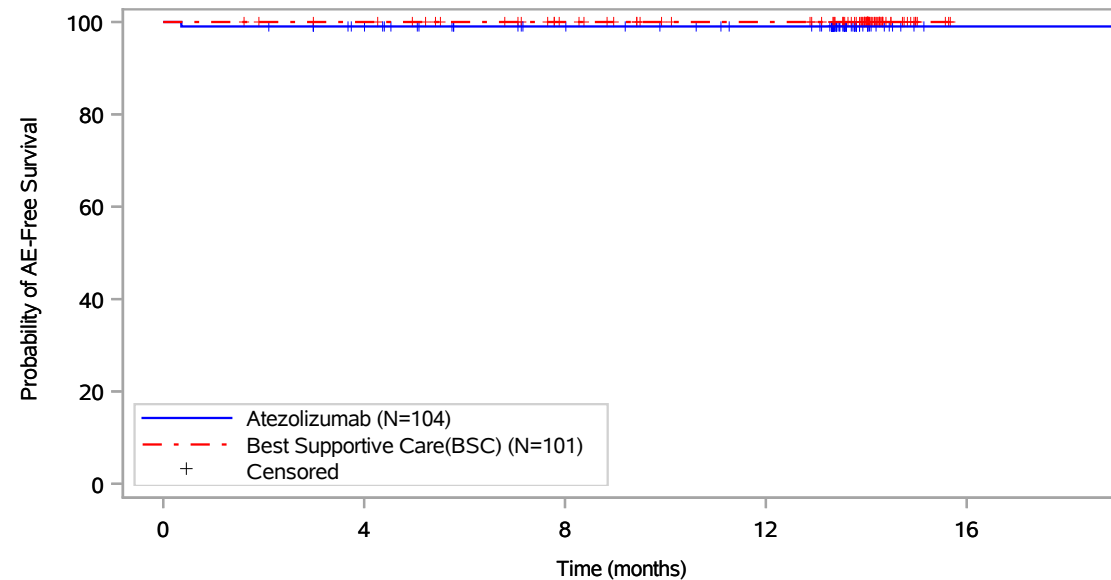
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	96	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMMIS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis
STUDY: GO29527



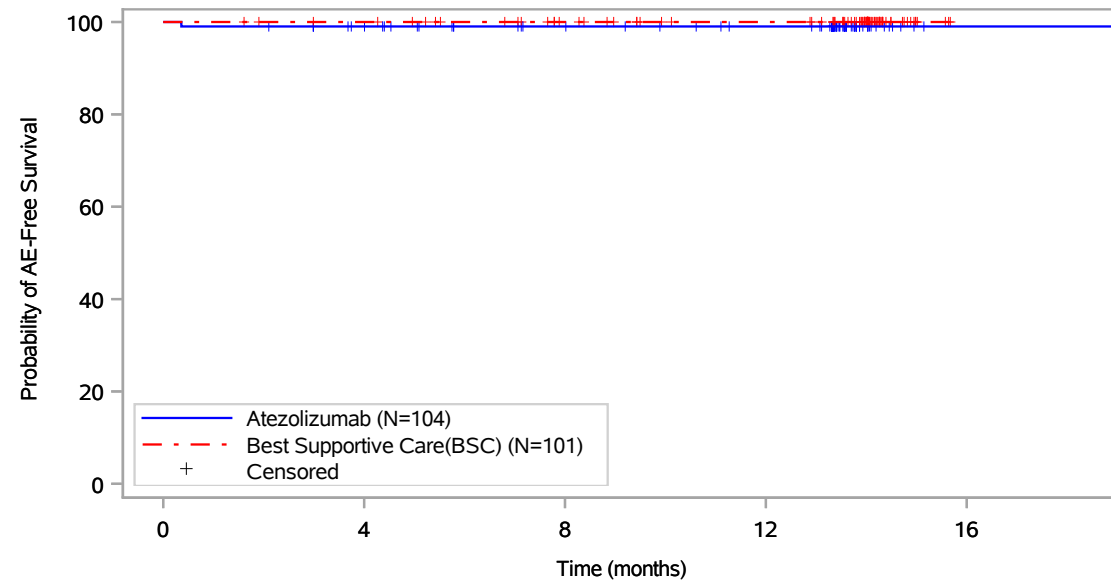
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIMEP_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:17

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis Grade \geq 3
STUDY: GO29527



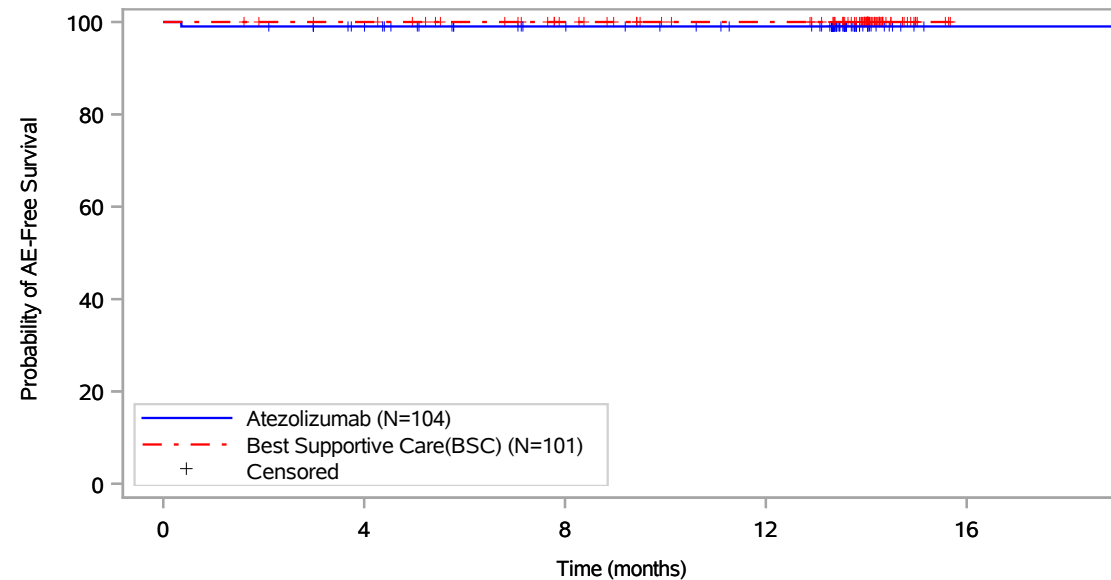
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..CE_DFS_IA/prod/output/g_km_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:20

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis Serious
STUDY: GO29527



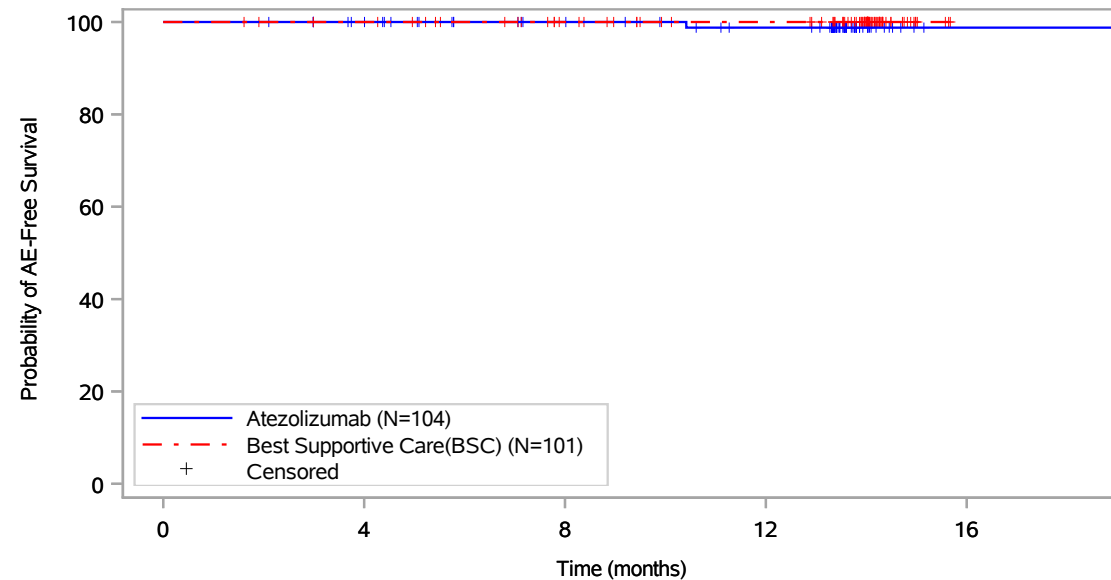
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMEPS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis
STUDY: GO29527



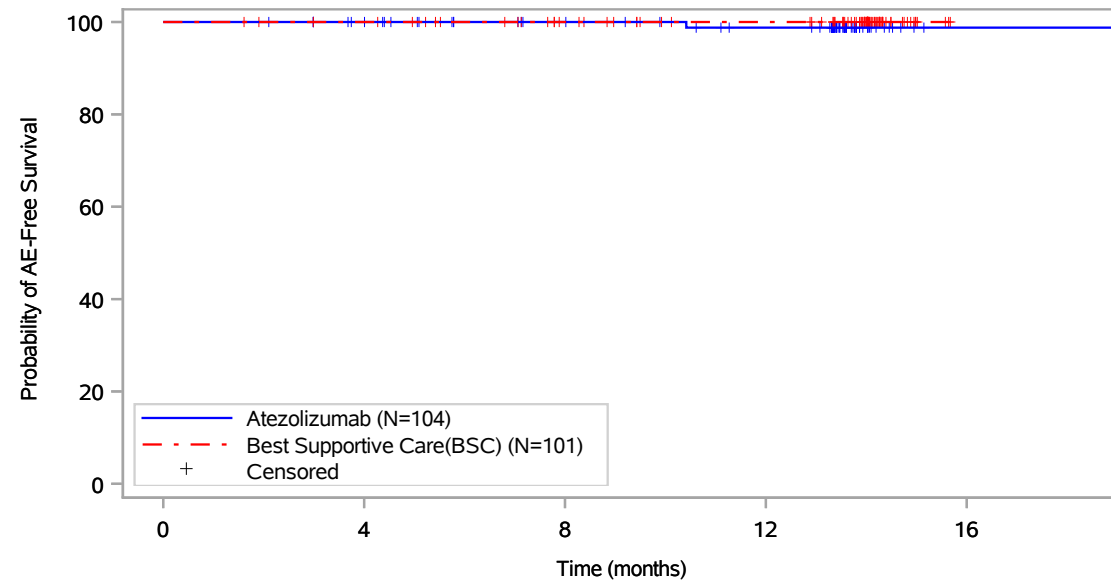
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis Grade \geq 3
STUDY: GO29527



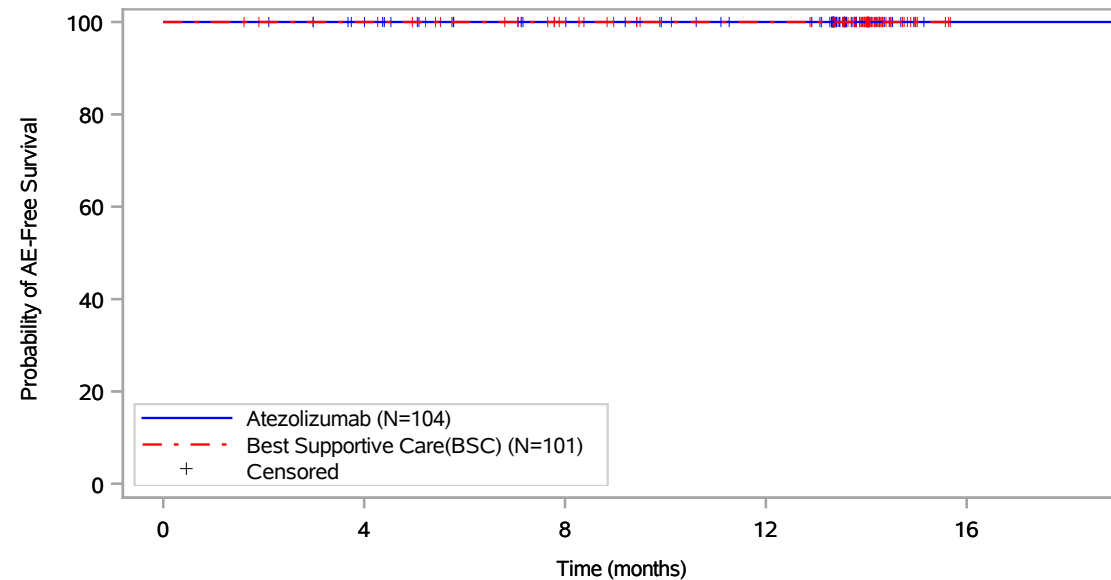
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...CE_DFS_IA/prod/output/g_km_TT1MCL35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:38

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis Serious
STUDY: GO29527



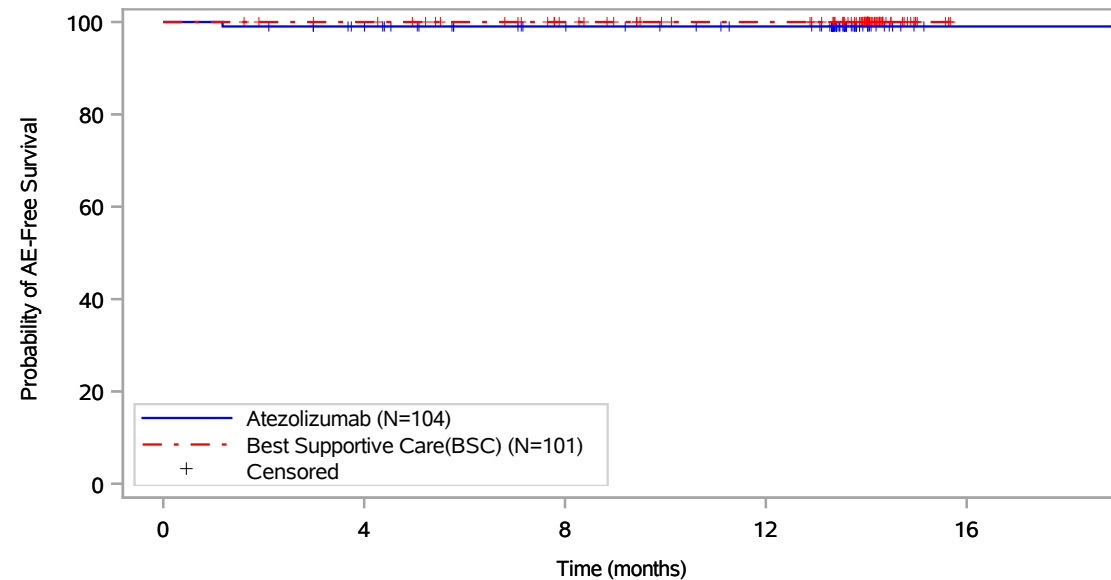
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome
STUDY: GO29527



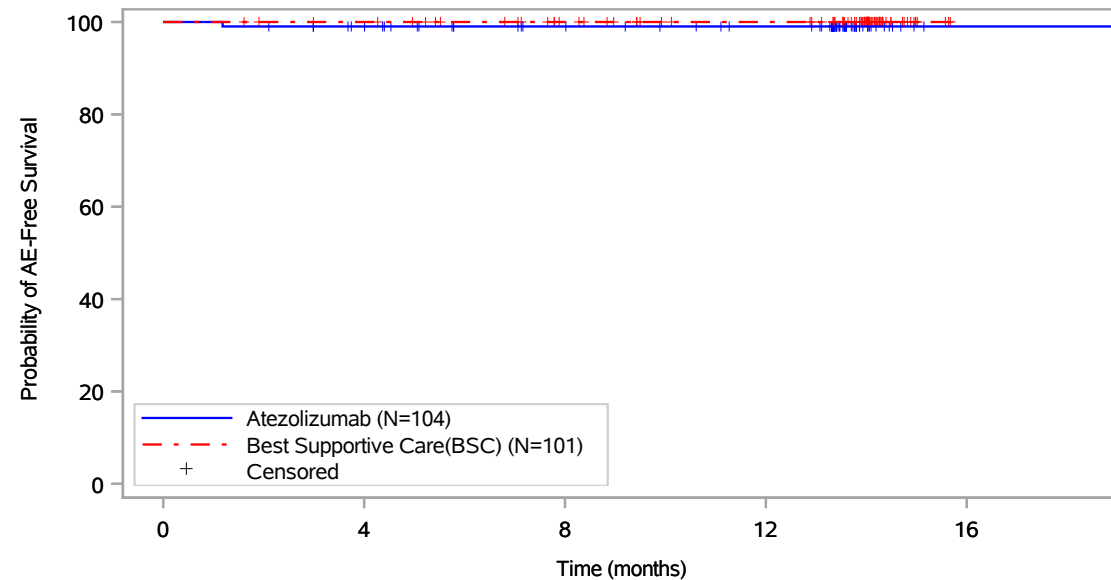
Patients at risk						
	0	4	8	12	16	
Atezolizumab (N=104)	104	97	85	79	1	
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE	
Patients censored						
Atezolizumab (N=104)	0	6	18	24	102	
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE	

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MGB_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Grade \geq 3
STUDY: GO29527



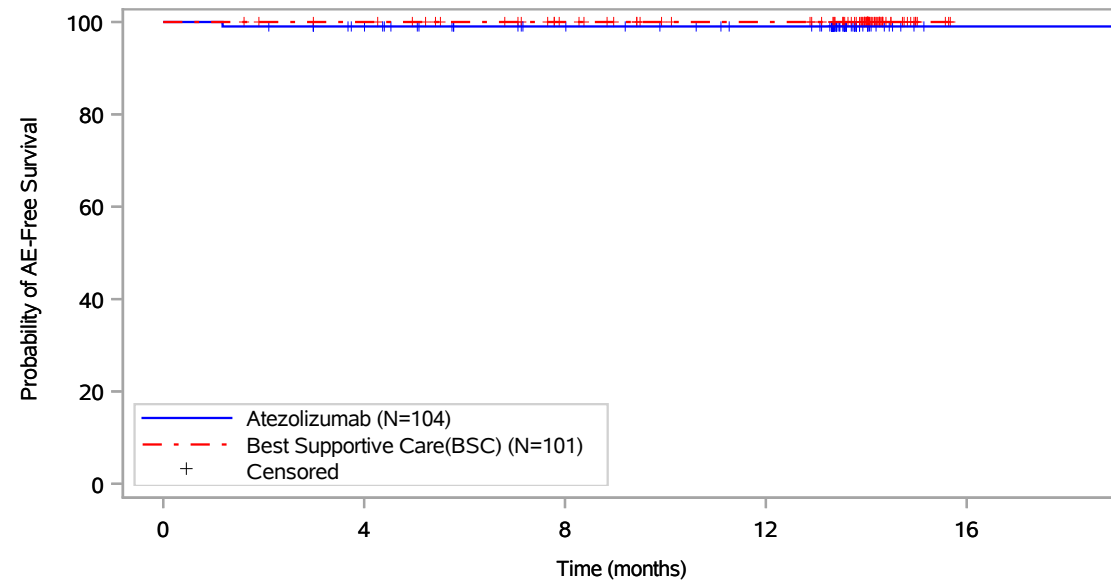
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..CE_DFS_IA/prod/output/g_km_TTIMGB35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:47

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Serious
STUDY: GO29527



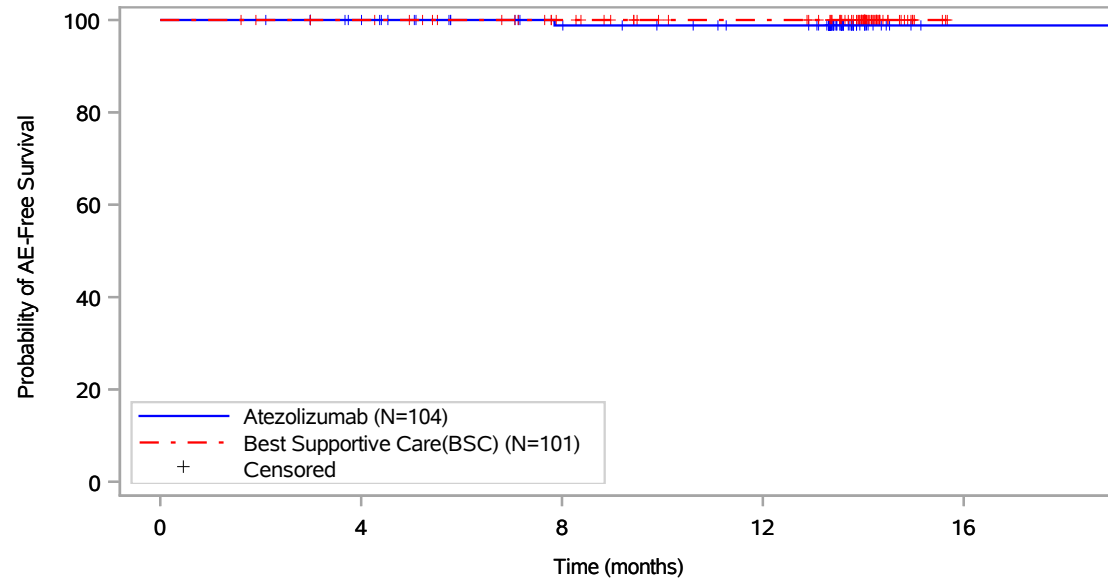
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	6	18	24	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMGBS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity
STUDY: GO29527



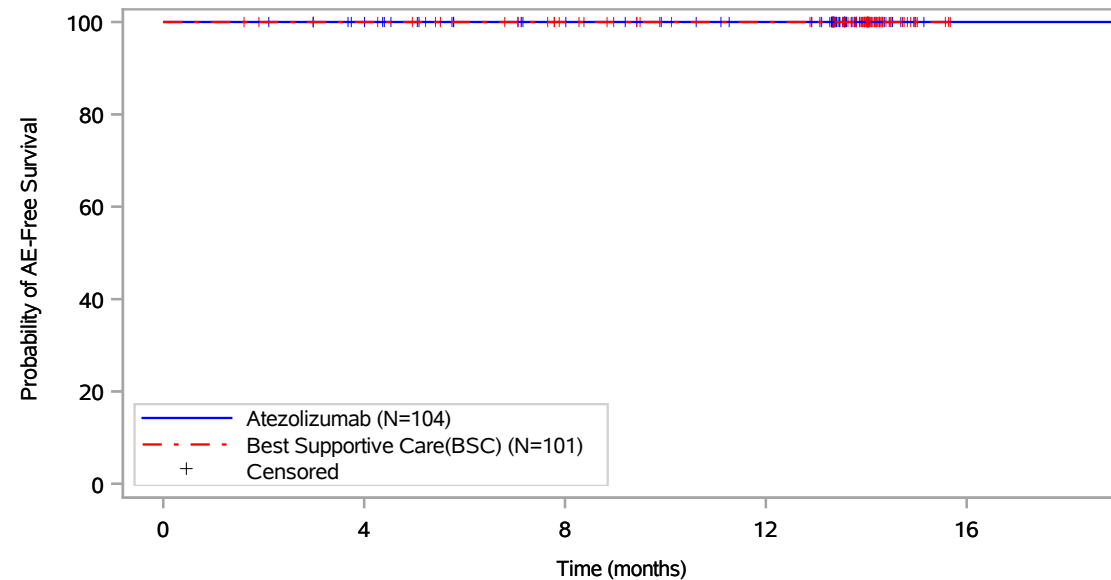
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	84	78	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	102
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Grade \geq 3
STUDY: GO29527



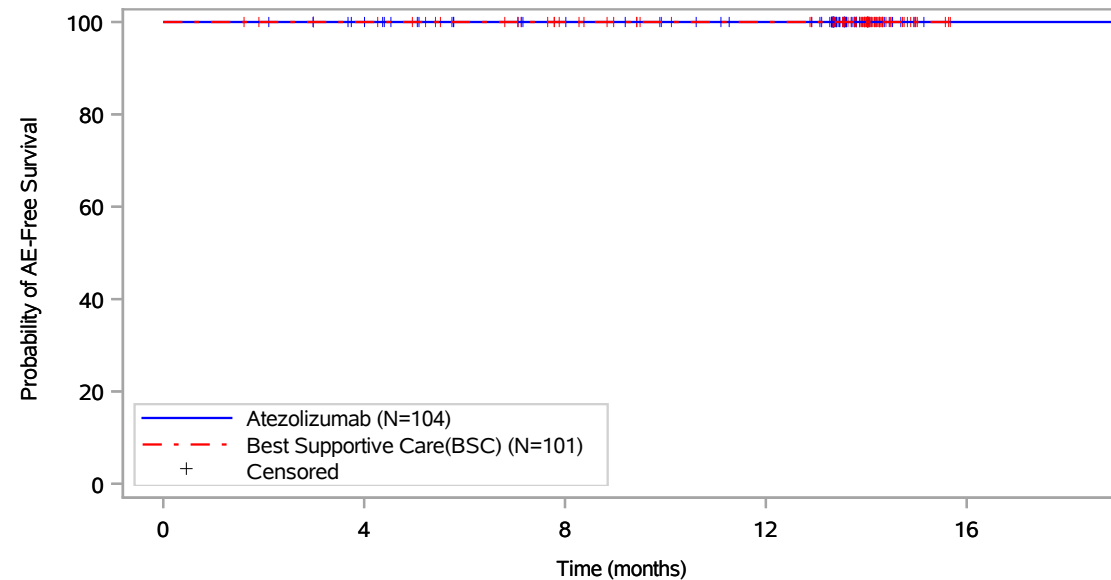
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..CE_DFS_IA/prod/output/g_km_TTIMOT35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Serious
STUDY: GO29527



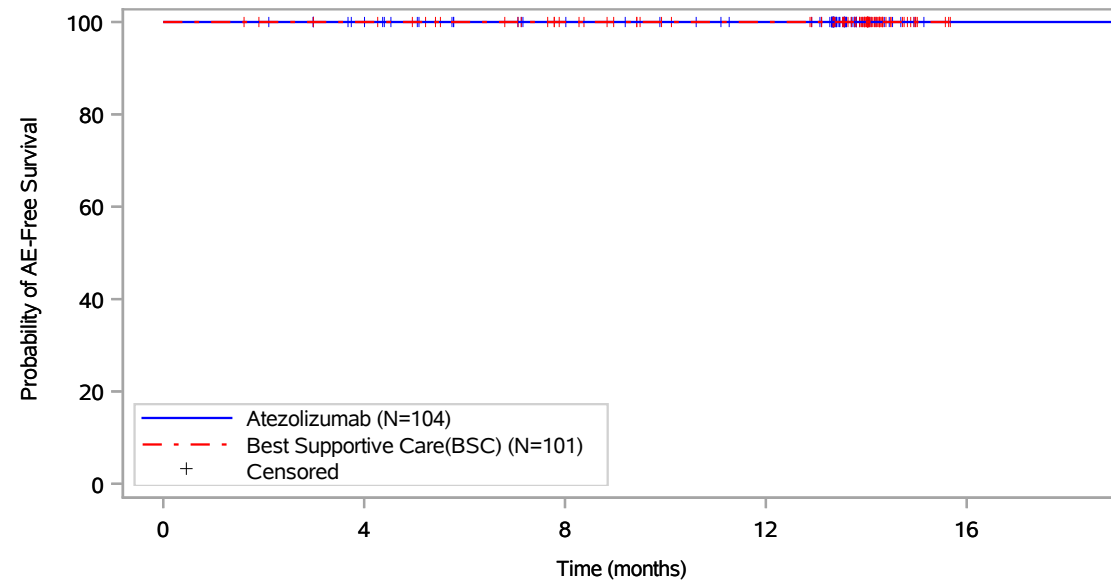
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_DFS_IA/prod/output/g_km_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Autoimmune Hemolytic Anemia
STUDY: GO29527



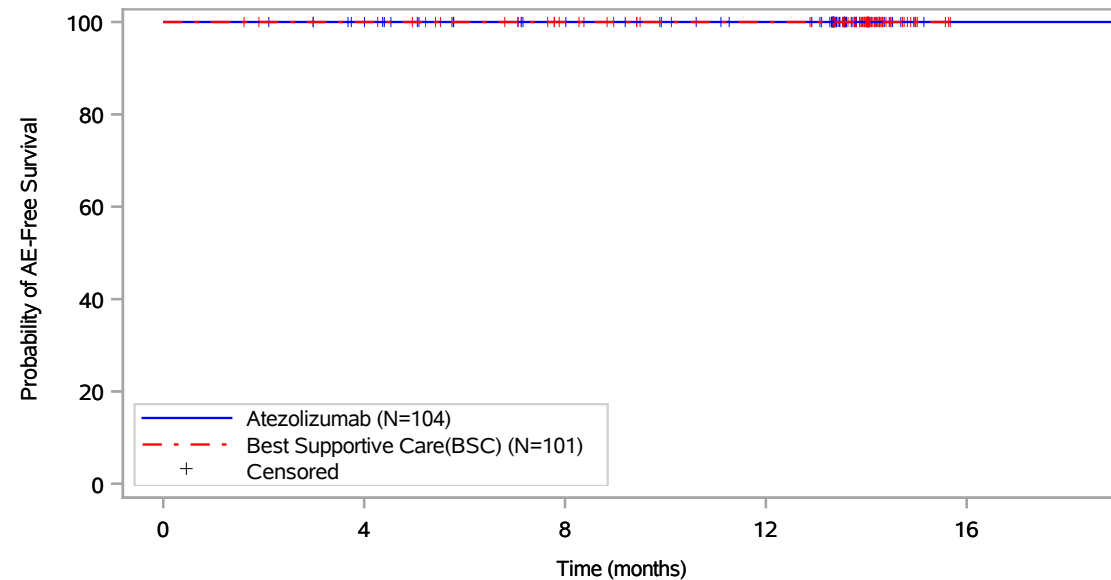
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s\ACE_DFS_IA/prod/output/g_km_TTAHA_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 22:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency
STUDY: GO29527



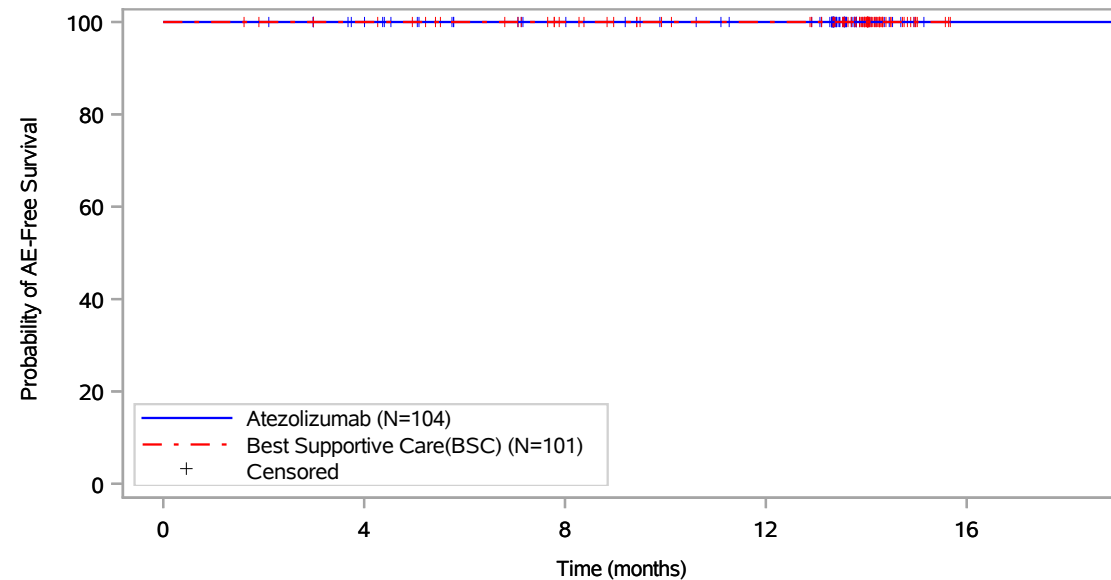
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MAI_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:18

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Diabetes mellitus
STUDY: GO29527



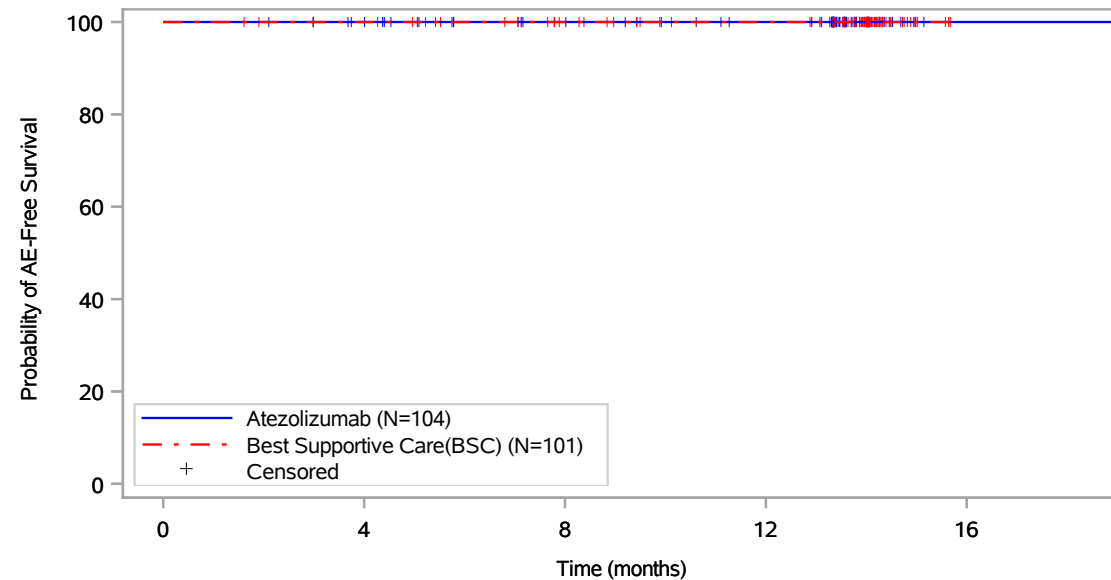
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MDM_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypophysitis
STUDY: GO29527



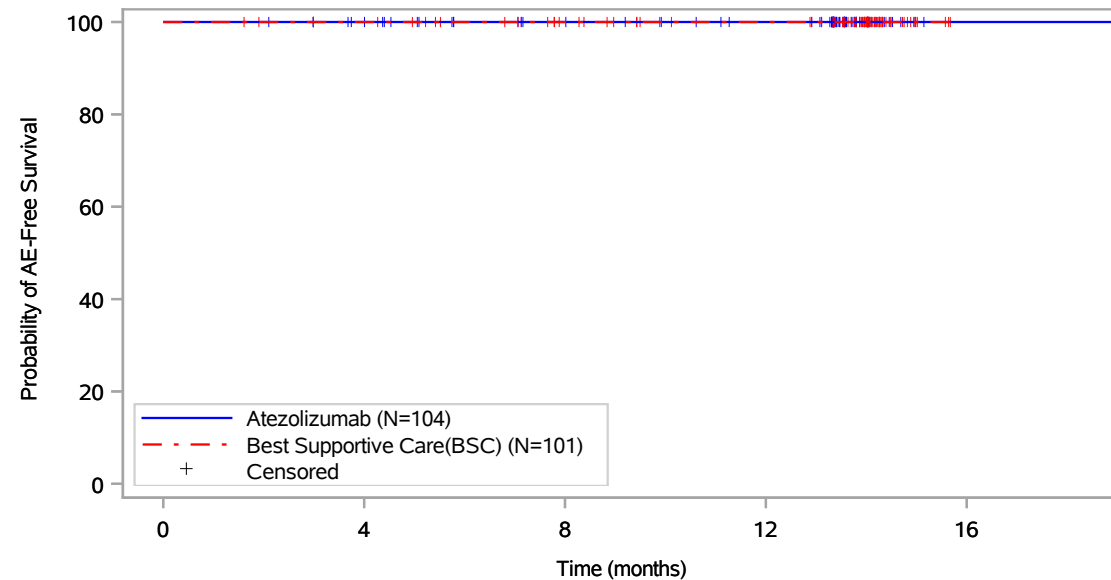
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MLH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis
STUDY: GO29527



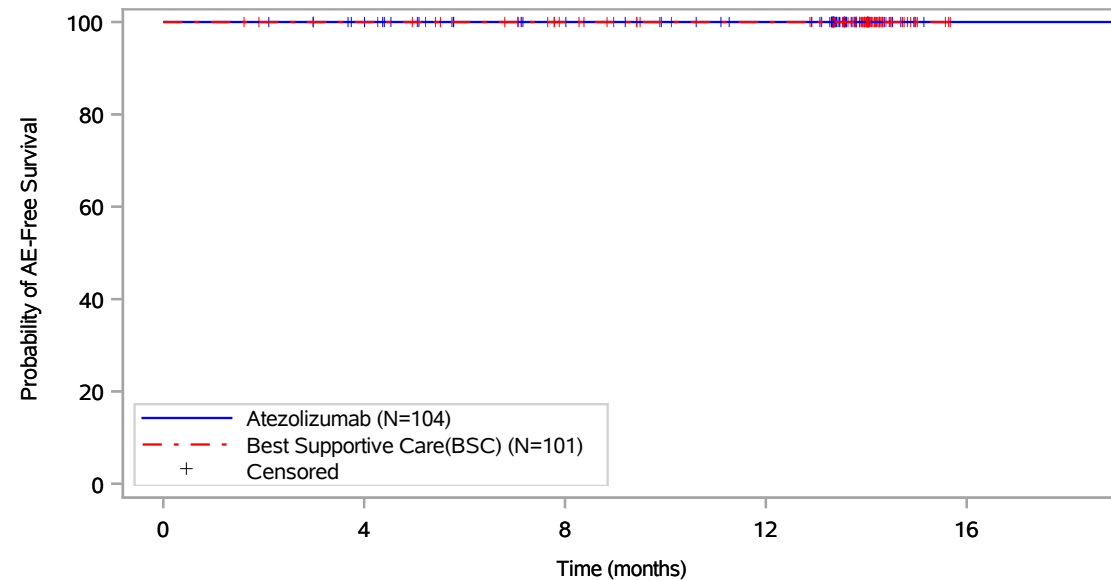
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MMG_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 19:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myocarditis
STUDY: GO29527



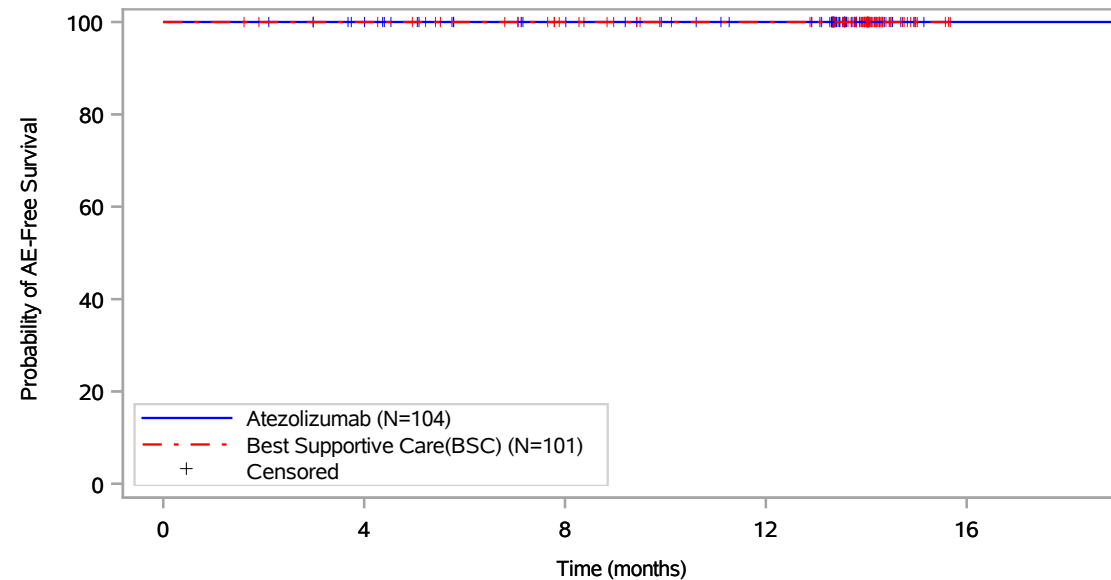
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIIMC_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:51

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myositis
STUDY: GO29527



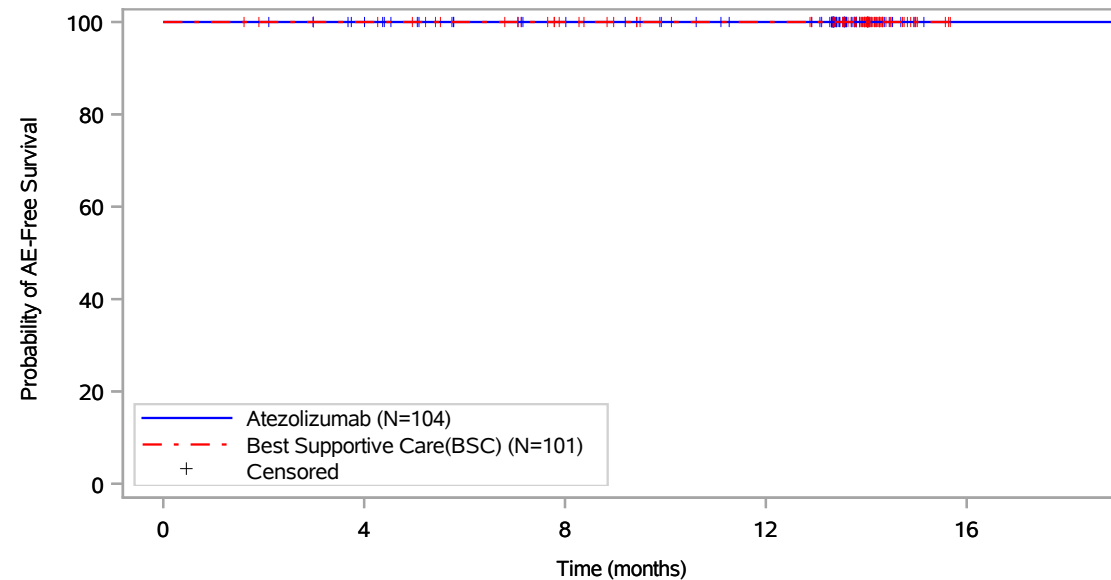
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIMMY_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:39

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Nephritis
STUDY: GO29527



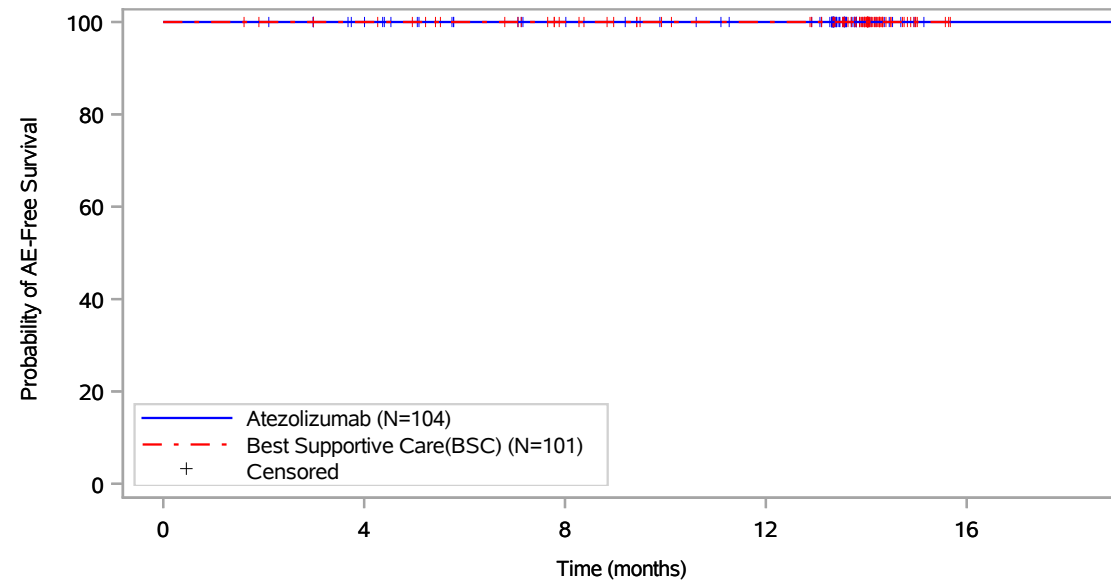
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIIMNP_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pancreatitis
STUDY: GO29527



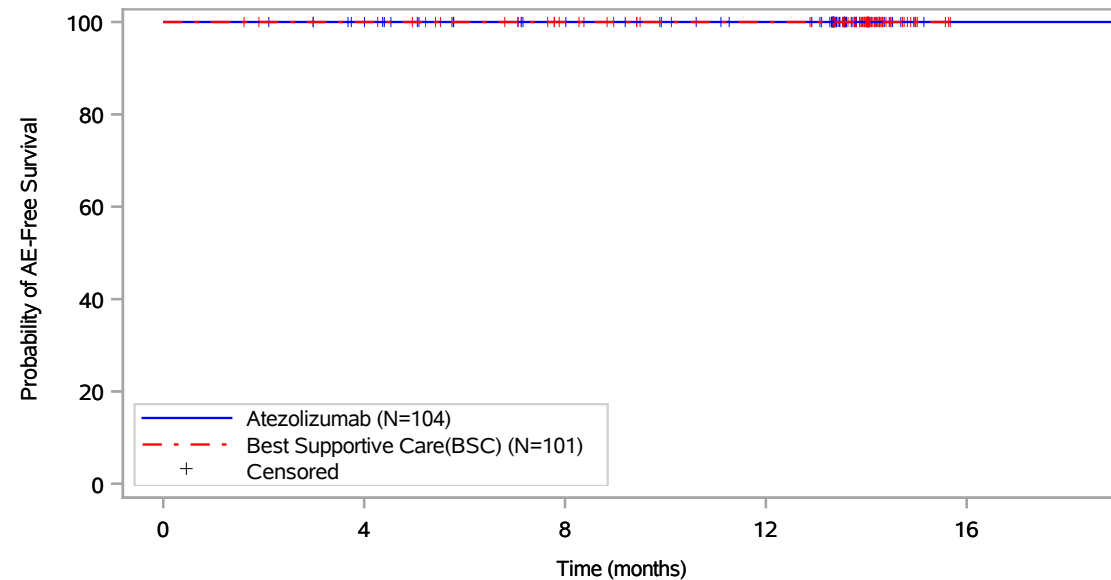
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTIIMPC_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Vasculitis
STUDY: GO29527



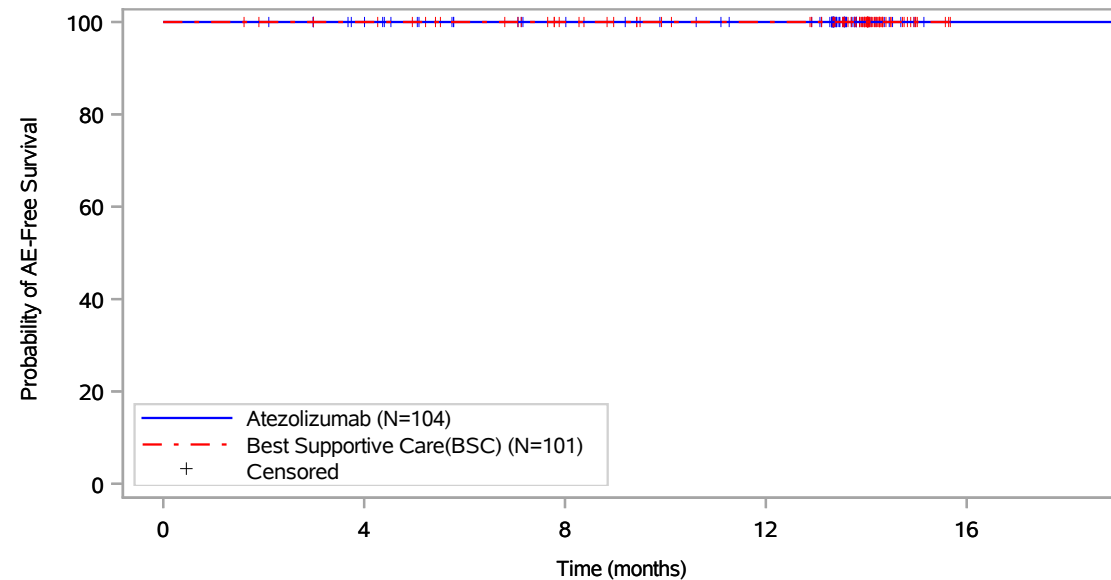
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TT1MVS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Infusion-Related Reactions
STUDY: GO29527



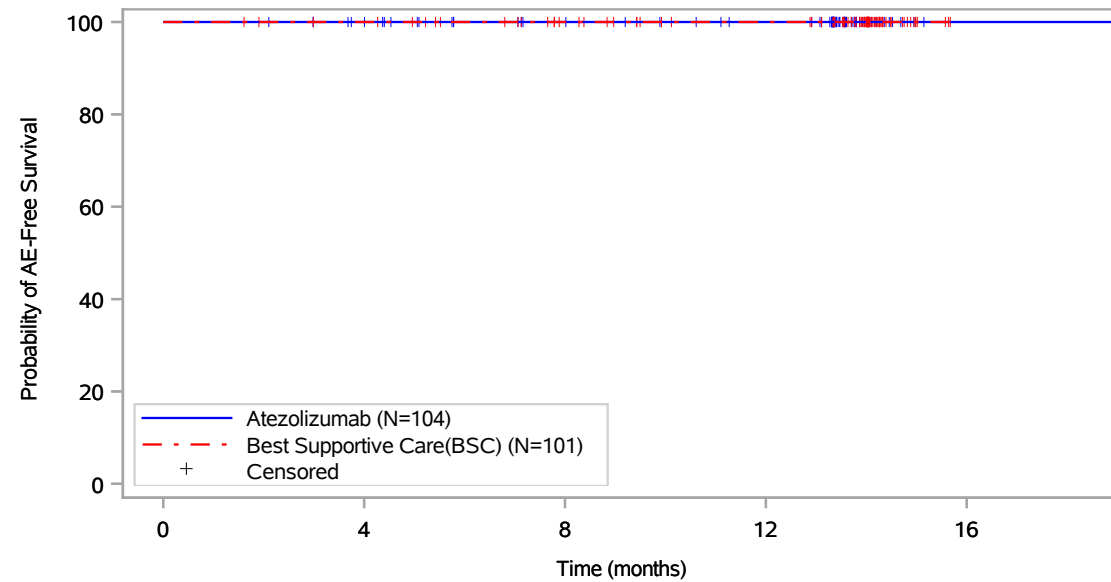
Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_DFS_IA/prod/output/g_km_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Rhabdomyolysis
STUDY: GO29527



Patients at risk					
	0	4	8	12	16
Atezolizumab (N=104)	104	97	85	79	1
Best Supportive Care(BSC) (N=101)	101	98	86	77	NE
Patients censored					
Atezolizumab (N=104)	0	7	19	25	103
Best Supportive Care(BSC) (N=101)	0	3	15	24	NE

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_DFS_IA/prod/output/g_km_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.pdf
 13DEC2021 21:48

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Spezifische Verträglichkeit

Outcome

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: All Patients
 MODEL: --
 STUDY: GO29527
 Outcome of Adverse Events of Special Interest

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care(BSC) (N=101)																	
	Total		RECOVERED /RESOLVED		RECOVERED /RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED /RESOLVED		RECOVERED /RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Immune-Mediated Hepatitis																																
All	23	20	87,0	1	4,3	0	0,0	0	0,0	2	8,7	0	0,0	0	0,0	8	6	75,0	0	0,0	2	25,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	15	14	93,3	0	0,0	0	0,0	0	0,0	1	6,7	0	0,0	0	0,0	8	6	75,0	0	0,0	2	25,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	2	1	50,0	1	50,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	6	5	83,3	0	0,0	0	0,0	0	0,0	1	16,7	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hepatitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Hypothyroidism																																
All	19	7	36,8	0	0,0	10	52,6	0	0,0	2	10,5	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	11	7	63,6	0	0,0	3	27,3	0	0,0	1	9,1	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	0	0,0	0	0,0	7	87,5	0	0,0	1	12,5	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hypothyroidism																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Hyperthyroidism																																
All	5	5	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	1	50,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hyperthyroidism																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)																	
Category of Adverse Events	Grade	Total		RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Immune-Mediated Adrenal insufficiency																																	
All		0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Adrenal insufficiency																																	
All		0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Pneumonitis																																	
All		6	5,83,3	0	0,0	0	0,0	0	0,0	1	16,7	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1		2	1,50,0	0	0,0	0	0,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2		3	3,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 4		1	1,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Pneumonitis																																	
All		2	2,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2		1	1,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 4		1	1,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Colitis																																	
All		1	1,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3		1	1,100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Colitis																																	
All		0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Guillain-Barre Syndrome																																	
All		1	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3		1	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Guillain-Barre Syndrome																																	
All		1	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3		1	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Myasthenia Gravis																																	

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)												Best Supportive Care (BSC) (N=101)																			
Category of Adverse Events	Grade	Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING			
		n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Myasthenia Gravis																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Meningoencephalitis																																	
All		2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3		2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Meningoencephalitis																																	
All		2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3		2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Infusion-Related Reactions																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Infusion-Related Reactions																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Pancreatitis																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Pancreatitis																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Diabetes mellitus																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Diabetes mellitus																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Myositis																																	
All		0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Vollständige Darstellung relevanter Ergebnisse

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)																							
	Total		RECOVERED /RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED /RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING							
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%						
Serious Immune-Mediated Myositis																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Rhabdomyolysis																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Rhabdomyolysis																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Nephritis																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Nephritis																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Rash																																						
All	26	18	69,2	1	3,8	7	26,9	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	17	14	82,4	1	5,9	2	11,8	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	3	37,5	0	0,0	5	62,5	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Rash																																						
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Meningitis																																						
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Meningitis																																						
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Encephalitis																																						
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)																	
Category of Adverse Events	Grade	Total		RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
		n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%		
Grade 3																																	
Serious Immune-Mediated Encephalitis																																	
All																																	
Grade 3																																	
Immune-Mediated Ocular Inflammatory Toxicity																																	
All																																	
Grade 1																																	
Serious Immune-Mediated Ocular Inflammatory Toxicity																																	
All																																	
Immune-Mediated Vasculitis																																	
All																																	
Serious Immune-Mediated Vasculitis																																	
All																																	
Immune-Mediated Hypophysitis																																	
All																																	
Serious Immune-Mediated Hypophysitis																																	
All																																	
Immune-Mediated Myocarditis																																	
All																																	
Serious Immune-Mediated Myocarditis																																	
All																																	
Immune-Mediated Severe Cutaneous Reactions																																	
All																																	
Grade 1																																	

Vollständige Darstellung relevanter Ergebnisse

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)																			
	Total	RECOVERED /RESOLVED		RECOVERED /RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING /RESOLVING		UNKNOWN		MISSING		Total	RECOVERED /RESOLVED		RECOVERED /RESOLVED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING /RESOLVING		UNKNOWN		MISSING					
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
Serious Immune-Mediated Severe Cutaneous Reactions																																		
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Autoimmune Hemolytic Anemia																																		
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Autoimmune Hemolytic Anemia																																		
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_resolved.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_resolved_aes_i_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xl
24FEB2022 15:44

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Verträglichkeit

Spezifische Verträglichkeit nach SOC/PT

Immunvermittelte Hepatitis nach SOC/PT (deskriptiv)

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	5	4,8	101	100,0	1	1,0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0,0
Hepatobiliary disorders	Hepatic steatosis	n/a	104	100,0	1	1,0	101	100,0	1	1,0
Hepatobiliary disorders	Hyperbilirubinaemia	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations		n/a	104	100,0	11	10,6	101	100,0	4	4,0
Investigations	Alanine aminotransferase increased	n/a	104	100,0	8	7,7	101	100,0	3	3,0
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	5	4,8	101	100,0	3	3,0
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	0	0,0	101	100,0	1	1,0
Investigations	Liver function test increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations	Transaminases increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations	Urine bilirubin increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:26

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	5	6,1	71	70,3	1	1,4
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Male	82	78,8	1	1,2	71	70,3	1	1,4
Hepatobiliary disorders	Hepatic steatosis	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	Male	82	78,8	1	1,2	71	70,3	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations		Male	82	78,8	9	11,0	71	70,3	3	4,2
Investigations		Female	22	21,2	2	9,1	30	29,7	1	3,3
Investigations	Alanine aminotransferase increased	Male	82	78,8	6	7,3	71	70,3	2	2,8
Investigations	Alanine aminotransferase increased	Female	22	21,2	2	9,1	30	29,7	1	3,3
Investigations	Aspartate aminotransferase increased	Male	82	78,8	4	4,9	71	70,3	2	2,8
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	1	3,3
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	0	0,0	71	70,3	1	1,4
Investigations	Gamma-glutamyltransferase increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Liver function test increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Liver function test increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Transaminases increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Transaminases increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Urine bilirubin increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Urine bilirubin increased	Female	22	21,2	0	0,0	30	29,7	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	4	6,3	62	61,4	1	1,6
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Hepatobiliary disorders	Hepatic steatosis	< 65	64	61,5	1	1,6	62	61,4	1	1,6
Hepatobiliary disorders	Hepatic steatosis	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations		< 65	64	61,5	8	12,5	62	61,4	4	6,5
Investigations		>= 65	40	38,5	3	7,5	39	38,6	0	0,0
Investigations	Alanine aminotransferase increased	< 65	64	61,5	5	7,8	62	61,4	3	4,8
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	3	7,5	39	38,6	0	0,0
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	3	4,7	62	61,4	3	4,8
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	2	5,0	39	38,6	0	0,0
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	0	0,0	62	61,4	1	1,6
Investigations	Gamma-glutamyltransferase increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Liver function test increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Liver function test increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Transaminases increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Transaminases increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Urine bilirubin increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Urine bilirubin increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	3	10,3	23	22,8	0	0,0
Hepatobiliary disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	1	1,5
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Europe and Middle East	65	62,5	0	0,0	68	67,3	1	1,5
Hepatobiliary disorders	Hepatic steatosis	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations		Asia Pacific and Australia	29	27,9	4	13,8	23	22,8	2	8,7
Investigations		Europe and Middle East	65	62,5	6	9,2	68	67,3	2	2,9
Investigations		North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	2	8,7
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	5	7,7	68	67,3	1	1,5
Investigations	Alanine aminotransferase increased	North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	1	4,3
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	3	4,6	68	67,3	2	2,9
Investigations	Aspartate aminotransferase increased	North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	1	4,3
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Gamma-glutamyltransferase increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Liver function test increased	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0,0
Investigations	Liver function test increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Liver function test increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Transaminases increased	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0,0
Investigations	Transaminases increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Investigations	Transaminases increased	North America	10	9,6	0	0,0	10	9,9	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Urine bilirubin increased	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0,0
Investigations	Urine bilirubin increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Urine bilirubin increased	North America	10	9,6	0	0,0	10	9,9	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Immune-Mediated Hepatitis

MODEL: Unstratified analysis

STUDY: G029527

Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	1	3,0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders		IIIA	46	44,2	5	10,9	53	52,5	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0,0
Hepatobiliary disorders	Hepatic steatosis	IIA	31	29,8	0	0,0	33	32,7	1	3,0
Hepatobiliary disorders	Hepatic steatosis	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Hepatic steatosis	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Hyperbilirubinaemia	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Investigations		IIA	31	29,8	3	9,7	33	32,7	4	12,1
Investigations		IIB	27	26,0	2	7,4	15	14,9	0	0,0
Investigations		IIIA	46	44,2	6	13,0	53	52,5	0	0,0
Investigations	Alanine aminotransferase increased	IIA	31	29,8	3	9,7	33	32,7	3	9,1
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	5	10,9	53	52,5	0	0,0
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	2	6,5	33	32,7	3	9,1
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	3	6,5	53	52,5	0	0,0
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	33	32,7	1	3,0
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Gamma-glutamyltransferase increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0
Investigations	Liver function test increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Liver function test increased	IIB	27	26,0	1	3,7	15	14,9	0	0,0
Investigations	Liver function test increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0
Investigations	Transaminases increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Transaminases increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Transaminases increased	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Investigations	Urine bilirubin increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Urine bilirubin increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Urine bilirubin increased	IIB	27	26,0	1	3,7	15	14,9	0	0,0
Investigations	Urine bilirubin increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	100,0	0	0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations		n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Alanine aminotransferase increased	n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	3	3,7	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0
Investigations		Male	82	78,8	1	1,2	71	70,3	0	0
Investigations		Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	71	70,3	0	0
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	71	70,3	0	0
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations		< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations		>= 65	40	38,5	1	2,5	39	38,6	0	0
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	1	2,5	39	38,6	0	0
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	0	0,0	39	38,6	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations		Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Investigations		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Investigations		North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Investigations	Alanine aminotransferase increased	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Aspartate aminotransferase increased	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations		IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations		IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations		IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations	Alanine aminotransferase increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	1	2,2	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Anzahl Zentren, Länder, Regionen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: --
 MODEL: descriptive
 STUDY: GO29527
 Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	100	100,0	209	100,0	19	100,0	209	100,0	3	100,0	209	100,0
with <10 patients per arm	100	100,0	209	100,0	16	84,2	122	58,4	0	NE	NE	NE
with >=10 patients per arm	0	NE	NE	NE	3	15,8	87	41,6	3	100,0	209	100,0

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
 Geographical regions: Asia Pacific and Australia, Europe and Middle East, North America
 'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
 'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
 '% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_center.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_center_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
 13DEC2021 14:28

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Nicht im Studienprotokoll vorgesehene antineoplastische Folgetherapien

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations, Patients with Recurrence
 ENDPOINT: Subsequent Non-Protocol Anti-Cancer Therapy
 MODEL: descriptive
 STUDY: GO29527

ATC Class Level 2 Other Treatment	Atezolizumab (N=21)	Best Supportive Care(BSC) (N=43)
Total number of patients with at least one treatment	15 (71.4%)	25 (58.1%)
Total number of treatments	41	56
ANTINEOPLASTIC AGENTS		
Total number of patients with at least one treatment	15 (71.4%)	25 (58.1%)
Total number of treatments	41	56
PEMBROLIZUMAB	3 (14.3%)	14 (32.6%)
CARBOPLATIN	8 (38.1%)	6 (14.0%)
DOCETAXEL	4 (19.0%)	6 (14.0%)
CISPLATIN	4 (19.0%)	5 (11.6%)
GEMCITABINE	5 (23.8%)	4 (9.3%)
PEMETREXED	3 (14.3%)	3 (7.0%)
PACLITAXEL	3 (14.3%)	1 (2.3%)
RAMUCIRUMAB	2 (9.5%)	1 (2.3%)
ATEZOLIZUMAB	0	2 (4.7%)
DURVALUMAB	1 (4.8%)	1 (2.3%)
ETOPOSIDE	1 (4.8%)	1 (2.3%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (4.8%)	1 (2.3%)
IPLIMUMAB	0	2 (4.7%)
VINORELBINE	2 (9.5%)	0
VINORELBINE TARTRATE	1 (4.8%)	1 (2.3%)
AFATINIB DIMALEATE	0	1 (2.3%)
BEVACIZUMAB	0	1 (2.3%)
CRIZOTINIB	1 (4.8%)	0
EPACADOSTAT	0	1 (2.3%)
GEMCITABINE HYDROCHLORIDE	0	1 (2.3%)
NINTEDANIB	0	1 (2.3%)
NIVOLUMAB	0	1 (2.3%)
OSIMERTINIB	0	1 (2.3%)
CARDIAC THERAPY		
Total number of patients with at least one treatment	3 (14.3%)	1 (2.3%)
Total number of treatments	4	1
PACLITAXEL	3 (14.3%)	1 (2.3%)

Vollständige Darstellung relevanter Ergebnisse

INVESTIGATIONAL DRUG		
Total number of patients with at least one treatment	0	1 (2.3%)
Total number of treatments	0	1
EPACADOSTAT	0	1 (2.3%)
OPHTHALMOLOGICALS		
Total number of patients with at least one treatment	0	1 (2.3%)
Total number of treatments	0	1
BEVACIZUMAB	0	1 (2.3%)

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_Base/prod/program/t_cm_fu.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_cm_fu_RECIPAT_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
01MAR2022 10:32

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Demographische und Baseline Charakteristika

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: --
 MODEL: descriptive
 STUDY: GO29527
 Demographics and Baseline Characteristics

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Age (yrs) at randomization			
n	106	103	209
Mean (SD)	60.9 (8.5)	61.2 (8.8)	61.1 (8.7)
Median	62	62	62
Min - Max	34 - 77	36 - 84	34 - 84
Age group 1 (yrs) at randomization			
n	106	103	209
< 65	65 (61.3%)	62 (60.2%)	127 (60.8%)
>= 65	41 (38.7%)	41 (39.8%)	82 (39.2%)
Age group 2 (yrs) at randomization			
n	106	103	209
< 65	65 (61.3%)	62 (60.2%)	127 (60.8%)
65 - 74	39 (36.8%)	38 (36.9%)	77 (36.8%)
75 - 84	2 (1.9%)	3 (2.9%)	5 (2.4%)
Sex per eCRF			
n	106	103	209
Male	84 (79.2%)	73 (70.9%)	157 (75.1%)
Female	22 (20.8%)	30 (29.1%)	52 (24.9%)
Sex per IxRS			
n	106	103	209
Male	84 (79.2%)	73 (70.9%)	157 (75.1%)
Female	22 (20.8%)	30 (29.1%)	52 (24.9%)
Race			
n	106	103	209
Asian	31 (29.2%)	24 (23.3%)	55 (26.3%)
Black or African American	1 (0.9%)	0	1 (0.5%)
Native Hawaiian or other Pacific Islander	1 (0.9%)	0	1 (0.5%)
White	71 (67.0%)	77 (74.8%)	148 (70.8%)
Unknown	2 (1.9%)	2 (1.9%)	4 (1.9%)

Vollständige Darstellung relevanter Ergebnisse

Ethnicity			
n	106	103	209
Hispanic or Latino	2 (1.9%)	2 (1.9%)	4 (1.9%)
Not Hispanic or Latino	102 (96.2%)	97 (94.2%)	199 (95.2%)
Not Stated	2 (1.9%)	3 (2.9%)	5 (2.4%)
Unknown	0	1 (1.0%)	1 (0.5%)
Weight (kg) at randomization*			
n	104	101	205
Mean (SD)	74.57 (16.87)	76.60 (18.49)	75.57 (17.67)
Median	72,25	75	73,4
Min - Max	46.6 - 132.5	43.5 - 126.3	43.5 - 132.5
ECOG performance status at randomization*			
n	106	103	209
0	66 (62.3%)	53 (51.5%)	119 (56.9%)
1	40 (37.7%)	49 (47.6%)	89 (42.6%)
2	0	1 (1.0%)	1 (0.5%)
Tobacco use history			
n	106	103	209
Never	11 (10.4%)	10 (9.7%)	21 (10.0%)
Current	16 (15.1%)	21 (20.4%)	37 (17.7%)
Previous	79 (74.5%)	72 (69.9%)	151 (72.2%)

* At randomization is defined as the last assessment value before the start of treatment date in the randomization period.
Clinical cut-off: 21JAN2021

Program: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_Base/prod/program/t_dm.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_DFS_IA/prod/output/t_dm_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
13DEC2021 14:33

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Lungenkarzinom Charakteristika

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Lung Cancer Molecular Profile
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)	All Patients (N=209)
Stage per eCRF			
n	106	103	209
STAGE IIA	31 (29.2%)	33 (32.0%)	64 (30.6%)
STAGE IIB	27 (25.5%)	15 (14.6%)	42 (20.1%)
STAGE IIIA	48 (45.3%)	55 (53.4%)	103 (49.3%)
Stage per IxRS			
n	106	103	209
STAGE IB	1 (0.9%)	0	1 (0.5%)
STAGE II	57 (53.8%)	46 (44.7%)	103 (49.3%)
STAGE IIIA	48 (45.3%)	57 (55.3%)	105 (50.2%)
Histology per eCRF			
n	106	103	209
Squamous	47 (44.3%)	45 (43.7%)	92 (44.0%)
Non-squamous	59 (55.7%)	58 (56.3%)	117 (56.0%)
Histology per IxRS			
n	106	103	209
Squamous	48 (45.3%)	45 (43.7%)	93 (44.5%)
Non-squamous	58 (54.7%)	58 (56.3%)	116 (55.5%)
Time since initial NSCLC diagnosis to first treatment in randomization (months)			
n	103	101	204
Mean (SD)	5.60 (1.11)	5.36 (1.30)	5.48 (1.21)
Median	5,32	5,22	5,29
Min - Max	3.7 - 8.9	2.6 - 10.1	2.6 - 10.1
EGFR mutation status			
n	106	103	209
Not Detected	57 (53.8%)	61 (59.2%)	118 (56.5%)
Unknown	49 (46.2%)	42 (40.8%)	91 (43.5%)
ALK mutation status			
n	106	103	209
No	56 (52.8%)	55 (53.4%)	111 (53.1%)

Vollständige Darstellung relevanter Ergebnisse

Unknown	50 (47.2%)	48 (46.6%)	98 (46.9%)
EGFR mutation or ALK mutation			
n	106	103	209
No	52 (49.1%)	54 (52.4%)	106 (50.7%)
Unknown	54 (50.9%)	49 (47.6%)	103 (49.3%)
KRAS mutation			
n	106	103	209
Detected	7 (6.6%)	4 (3.9%)	11 (5.3%)
Not Detected	7 (6.6%)	5 (4.9%)	12 (5.7%)
Unknown	92 (86.8%)	94 (91.3%)	186 (89.0%)
Type of surgery			
n	106	103	209
Lobectomy	76 (71.7%)	74 (71.8%)	150 (71.8%)
Sleeve lobectomy	2 (1.9%)	1 (1.0%)	3 (1.4%)
Bilobectomy	7 (6.6%)	7 (6.8%)	14 (6.7%)
Pneumonectomy	20 (18.9%)	20 (19.4%)	40 (19.1%)
Other	1 (0.9%)	1 (1.0%)	2 (1.0%)

Patients not tested for a specific mutation are listed with "unknown" status.

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_dm_lung.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_dm_lung_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
13DEC2021 15:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Lung Cancer History
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Largest Tumor Diameter (cm)			
n	106	103	209
Mean (SD)	4.56 (2.38)	4.77 (2.55)	4.67 (2.46)
Median	4,1	4,2	4,2
Min - Max	1.0 - 13.5	1.0 - 12.5	1.0 - 13.5
Site of Primary Tumor			
n	106	103	209
LEFT	48 (45.3%)	41 (39.8%)	89 (42.6%)
RIGHT	58 (54.7%)	62 (60.2%)	120 (57.4%)
Subtype Histology in Non-Squamous			
n	59	58	117
ADENOCARCINOMA	56 (94.9%)	54 (93.1%)	110 (94.0%)
LARGE CELL	3 (5.1%)	2 (3.4%)	5 (4.3%)
UNDIFFERENTIATED	0	2 (3.4%)	2 (1.7%)
Primary Tumor Stage			
n	106	103	209
T1A	11 (10.4%)	11 (10.7%)	22 (10.5%)
T1B	14 (13.2%)	5 (4.9%)	19 (9.1%)
T2A	27 (25.5%)	37 (35.9%)	64 (30.6%)
T2B	15 (14.2%)	18 (17.5%)	33 (15.8%)
T3	35 (33.0%)	25 (24.3%)	60 (28.7%)
T4	4 (3.8%)	6 (5.8%)	10 (4.8%)
TX	0	1 (1.0%)	1 (0.5%)
Regional Lymph Node Stage (pN)			
n	106	103	209
N0	30 (28.3%)	20 (19.4%)	50 (23.9%)
N1	39 (36.8%)	43 (41.7%)	82 (39.2%)
N2	37 (34.9%)	40 (38.8%)	77 (36.8%)
Regional Lymph Node Positive			

Vollständige Darstellung relevanter Ergebnisse

n	106	103	209
Yes	76 (71.7%)	83 (80.6%)	159 (76.1%)
No	30 (28.3%)	20 (19.4%)	50 (23.9%)
Distant Metastasis Stage (pM)			
n	106	103	209
M0	106 (100%)	103 (100%)	209 (100%)
Stage of Initial Diagnosis			
n	106	103	209
STAGE IIA	31 (29.2%)	33 (32.0%)	64 (30.6%)
STAGE IIB	27 (25.5%)	15 (14.6%)	42 (20.1%)
STAGE IIIA	48 (45.3%)	55 (53.4%)	103 (49.3%)
Final Microscopic Margin			
n	106	103	209
NEGATIVE	106 (100%)	103 (100%)	209 (100%)

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_mh_lung.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_mh_lung_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
13DEC2021 15:21

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Lungenkarzinom Operation Charakteristika

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Lung Cancer Surgery
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Total number of patients with at least one surgery	106 (100%)	103 (100%)	209 (100%)
Total number of surgeries	107	105	212
Surgical procedure			
LOBECTOMY	76 (71.7%)	74 (71.8%)	150 (71.8%)
BILOBECTOMY	7 (6.6%)	7 (6.8%)	14 (6.7%)
PNEUMONECTOMY	20 (18.9%)	20 (19.4%)	40 (19.1%)
SLEEVE LOBECTOMY	2 (1.9%)	1 (1.0%)	3 (1.4%)
OTHER	2 (1.9%)	2 (1.9%)	4 (1.9%)
Time since last surgery to first treatment in enrollment period (months)			
n	106	103	209
Mean (SD)	1.88 (0.55)	1.76 (0.50)	1.82 (0.53)
Median	1,81	1,68	1,74
Min - Max	1.0 - 4.0	0.8 - 3.0	0.8 - 4.0
Time since last surgery to first treatment in randomization period (months)			
n	104	101	205
Mean (SD)	5.28 (0.78)	4.95 (0.92)	5.12 (0.86)
Median	5,22	5,03	5,13
Min - Max	3.5 - 7.7	2.3 - 7.2	2.3 - 7.7
Time since diagnosis to last surgery (months)			
n	105	103	208
Mean (SD)	0.35 (0.71)	0.44 (0.87)	0.40 (0.79)
Median	0,03	0,03	0,03
Min - Max	-0.9 - 3.3	-0.9 - 4.1	-0.9 - 4.1
Mediastinal lymph node dissection			
Yes	88 (83.0%)	84 (81.6%)	172 (82.3%)
No	18 (17.0%)	19 (18.4%)	37 (17.7%)
Lymph node sampling conduction			
Yes	18 (17.0%)	20 (19.4%)	38 (18.2%)
No	1 (0.9%)	2 (1.9%)	3 (1.4%)
Location of lung surgery			
RIGHT	57 (53.8%)	63 (61.2%)	120 (57.4%)

Vollständige Darstellung relevanter Ergebnisse

LEFT	49 (46.2%)	42 (40.8%)	91 (43.5%)
BILATERAL	1 (0.9%)	0	1 (0.5%)
Levels of thoracotomy			
Right thoracotomy level 4	51 (48.1%)	58 (56.3%)	109 (52.2%)
Right thoracotomy level 7	55 (51.9%)	56 (54.4%)	111 (53.1%)
Left thoracotomy level 5/6	41 (38.7%)	40 (38.8%)	81 (38.8%)
Left thoracotomy level 7	37 (34.9%)	38 (36.9%)	75 (35.9%)

Percentages are based on N in the column headings.
Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_xp_lung.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_xp_lung_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
13DEC2021 15:28

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Zeit von Operation bis Beginn Chemotherapie

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time from Surgery to start of Chemotherapy [Days]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)
n	106	103
Median	55	51
Min - Max	31 - 121	24 - 91
<= 60	68 (64.2%)	68 (66.0%)
> 60	38 (35.8%)	35 (34.0%)

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_surgtrt1.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_surgtrt1_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
13DEC2021 15:15

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Lokalisation von Tumorrezidiven

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Number and Percentage of Localization of Tumor Recurrences
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Localization of Tumor Recurrences*			
Distant Lung Cancer Recurrence	8 (7.5%)	26 (25.2%)	34 (16.3%)
Local Lung Cancer Recurrence	4 (3.8%)	6 (5.8%)	10 (4.8%)
Regional Lung Cancer Recurrence	9 (8.5%)	8 (7.8%)	17 (8.1%)
Second Primary Lung Cancer	0	3 (2.9%)	3 (1.4%)
Total	21 (19.8%)	43 (41.7%)	64 (30.6%)

* identified in variable DFS.

Percentages are based on N in the column headings.

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_recur.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_recur_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls

13DEC2021 15:18

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Studienabbruch

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: --
 MODEL: descriptive
 STUDY: GO29527
 Patients who Discontinued Study including Reason

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Received Treatment	104 (98.1%)	101 (98.1%)	205 (98.1%)
On-study	91 (85.8%)	73 (70.9%)	164 (78.5%)
Alive: In Follow-Up	91 (85.8%)	73 (70.9%)	164 (78.5%)
Discontinued Study	15 (14.2%)	30 (29.1%)	45 (21.5%)
Death	10 (9.4%)	24 (23.3%)	34 (16.3%)
Withdrawal by Subject	5 (4.7%)	5 (4.9%)	10 (4.8%)
Physician Decision	0	1 (1.0%)	1 (0.5%)

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ds_study.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ds_study_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
 13DEC2021 14:45

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Behandlungsabbruch

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: --
 MODEL: descriptive
 STUDY: GO29527
 Patients who Discontinued Treatment including Reason

	Atezolizumab (N=104)	Best Supportive Care (BSC) (N=101)	All Patients (N=205)
Atezo/BSC Treatment Status			
Completed	77 (74.0%)	74 (73.3%)	151 (73.7%)
Discontinued	27 (26.0%)	27 (26.7%)	54 (26.3%)
Atezo/BSC Treatment Discontinuation Reason			
Adverse Event	20 (19.2%)	1 (1.0%)	21 (10.2%)
Protocol Deviation	0	1 (1.0%)	1 (0.5%)
Withdrawal by Subject	5 (4.8%)	2 (2.0%)	7 (3.4%)
Disease Relapse	2 (1.9%)	23 (22.8%)	25 (12.2%)

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ds_trt.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ds_trt_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 13DEC2021 14:49

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Anzahl erhaltener Chemotherapiezyklen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Number of Chemotherapy Cycles
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)
Number of Cisplatin Cycles		
n	106	103
Mean (SD)	3.8 (0.5)	3.6 (0.9)
Median	4	4
Min - Max	2 - 4	1 - 4
1 Cycle	0	7 (6.8%)
2 Cycles	5 (4.7%)	6 (5.8%)
3 Cycles	9 (8.5%)	6 (5.8%)
4 Cycles	92 (86.8%)	84 (81.6%)
Number of Docetaxel Cycles		
n	13	19
Mean (SD)	4.0 (0.0)	3.8 (0.5)
Median	4	4
Min - Max	4 - 4	2 - 4
2 Cycles	0	1 (5.3%)
3 Cycles	0	1 (5.3%)
4 Cycles	13 (100%)	17 (89.5%)
Number of Gemcitabine Cycles		
n	20	16
Mean (SD)	3.9 (0.5)	3.1 (1.2)
Median	4	4
Min - Max	2 - 4	1 - 4
1 Cycle	0	2 (12.5%)
2 Cycles	1 (5.0%)	4 (25.0%)
3 Cycles	1 (5.0%)	0
4 Cycles	18 (90.0%)	10 (62.5%)
Number of Pemetrexed Cycles		
n	29	32
Mean (SD)	3.9 (0.3)	3.6 (0.9)
Median	4	4

Vollständige Darstellung relevanter Ergebnisse

Min - Max	3 - 4	1 - 4
1 Cycle	0	3 (9.4%)
2 Cycles	0	1 (3.1%)
3 Cycles	2 (6.9%)	1 (3.1%)
4 Cycles	27 (93.1%)	27 (84.4%)
Number of Vinorelbine Cycles		
n	44	36
Mean (SD)	3.7 (0.6)	3.8 (0.6)
Median	4	4
Min - Max	2 - 4	1 - 4
1 Cycle	0	1 (2.8%)
2 Cycles	4 (9.1%)	1 (2.8%)
3 Cycles	6 (13.6%)	3 (8.3%)
4 Cycles	34 (77.3%)	31 (86.1%)

Patients are counted to Gemcitabine Cycle if they get a least one of the two scheduled doses.

Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ex_cyc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ex_cyc_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
02MAR2022 13:50

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Dauer des Survival Follow-up

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Efficacy Follow-up [Months]
 MODEL: descriptive
 STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)
n	106	103
Mean (SD)	35.10 (9.31)	32.10 (11.81)
Median	35,86	33,87
25% and 75%-ile	29.70 - 40.21	26.81 - 41.00
Min - Max	0.1 - 54.6	0.2 - 58.0

Only randomization period was considered.

Efficacy Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date) - Randomization Date.
 Clinical cut-off: 21JAN2021

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_fu_FUEFF_EGFRALKNOUK_SP263T3_ST23_IT_21JAN2021_29527.xls
 13DEC2021 15:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Safety Follow-up at 30 Days [Months]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=104)	Best Supportive Care (BSC) (N=101)
n	104	101
Mean (SD)	9.84 (3.58)	10.67 (2.94)
Median	11,33	12,02
25% and 75%-ile	11.09 - 11.60	10.91 - 12.25
Min - Max	1.0 - 17.0	1.0 - 13.7

Only randomization period was considered.

Safety Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date, Date of Last Dose of Study Treatment + 30 Days (Date of Last Study Assessment for Patients in Arm BSC), Initiation of Subsequent Anti-Cancer Therapy) - Treatment Start Date.
Clinical cut-off: 21JAN2021

Program: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_fu_AER30_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
13DEC2021 15:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Safety Follow-up at 90 Days [Months]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=104)	Best Supportive Care (BSC) (N=101)
n	104	101
Mean (SD)	11.78 (3.65)	12.38 (3.32)
Median	13,31	13,96
25% and 75%-ile	12.96 - 13.57	12.88 - 14.19
Min - Max	2.1 - 18.9	1.6 - 15.6

Only randomization period was considered.

Safety Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date, Date of Last Dose of Study Treatment + 90 Days (Date of Last Study Assessment for Patients in Arm BSC), Initiation of Subsequent Anti-Cancer Therapy) - Treatment Start Date.
Clinical cut-off: 21JAN2021

Program: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_fu_AER90_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
13DEC2021 15:11

Endpunkte der Studie IMpower010

Zulassungsdatenschnitt 21.01.2021

Sonstige Analysen

Umkodierung Tumorklassifikation UICC 7 zu UICC 8

Vollständige Darstellung relevanter Ergebnisse

	nach UICC 7		nach UICC 8		Anzahl Patient:innen in der Zulassungspopulation N=209 n (%)
	T N	Stadium	T N	Stadium	
Tumorbeschreibung in Kombination mit N0					
< 1 cm	T1 N0	IA	T1a N0	IA1	---
> 1–2 cm	T1 N0	IA	T1b N0	IA2	---
> 2–3 cm	T1 N0	IA	T1c N0	IA3	---
> 3–4 cm, Infiltration der viszerale Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina, Tumore die zu einer partiellen Atelektasen oder Pneumonitis führen	T2a N0	IB	T2a N0	IB	---
> 4–5 cm, Infiltration der viszerale Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina; Tumore die zu einer partiellen Atelektase oder Pneumonitis führen	T2a N0	IB	T2b N0	IIA	---
> 5–7 cm	T2b N0	IIA	T3 N0	IIB	12 (5,7 %)
> 7cm	T3 N0	IIB	T4 N0	IIIA	15 (7,2 %)
Infiltration der Brustwand, des Nervus phrenicus, der mediastinalen Pleura oder des parietalen Herzbeutels	T3 N0	IIB	T3 N0	IIB	17 (8,1 %)
Infiltration des Zwerchfells			T4 N0	IIIA	
Infiltration des Hauptbronchus mit < 2 cm Abstand zu der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore bis 4 cm			T2a N0	IB	
Infiltration des Hauptbronchus < 2 cm distal der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore 4–5 cm			T2b N0	IIA	
Infiltration des Mediastinum, des Herz, der großen Gefäße, der Luftröhre, des Nervus laryngeus recurrence, der Speiseröhre, der Wirbelkörper oder der Karina; Tumore mit separatem Knoten im gleichen oder einem anderem ipsilateralen Lappen als dem primären	T4 N0	IIIA	T4 N0	IIIA	6 (2,9 %)

Vollständige Darstellung relevanter Ergebnisse

	nach UICC 7		nach UICC 8		Anzahl Patient:innen in der Zulassungspopulation N=209 n (%)
	T N	Stadium	T N	Stadium	
Tumorbeschreibung in Kombination mit N1					
< 1 cm	T1 N1	IIA	T1a N1	IIB	0
> 1–2 cm	T1 N1	IIA	T1b N1	IIB	8 (3,8 %)
> 2–3 cm	T1 N1	IIA	T1c N1	IIB	12 (5,7 %)
> 3–4 cm, Infiltration der viszeralen Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina, Tumore die zu einer partiellen Atelektasen oder Pneumonitis führen	T2a N1	IIA	T2a N1	IIB	23 (11,0 %)
> 4–5 cm, Infiltration der viszeralen Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina; Tumore die zu einer partiellen Atelektase oder Pneumonitis führen	T2a N1	IIA	T2b N1	IIB	9 (4,3 %)
> 5–7 cm	T2b N1	IIB	T3 N1	IIIA	10 (4,8 %)
> 7cm	T3 N1	IIIA	T4 N1	IIIA	6 (2,9 %)
Infiltration der Brustwand, des Nervus phrenicus, der mediastinalen Pleura oder des parietalen Herzbeutels	T3 N1	IIIA	T3 N1	IIIA	10 (4,8 %)
Infiltration des Zwerchfells			T4 N1	IIIA	
Infiltration des Hauptbronchus mit < 2 cm Abstand zu der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore bis 4 cm			T2a N1	IIB	
Infiltration des Hauptbronchus < 2 cm distal der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore 4–5 cm			T2b N1	IIB	
Infiltration des Mediastinum, des Herz, der großen Gefäße, der Luftröhre, des Nervus laryngeus recurrence, der Speiseröhre, der Wirbelkörper oder der Karina; Tumore mit separatem Knoten im gleichen oder einem anderem ipsilateralen Lappen als dem primären	T4 N1	IIIA	T4 N1	IIIA	4 (1,9 %)

Vollständige Darstellung relevanter Ergebnisse

	nach UICC 7		nach UICC 8		Anzahl Patient:innen in der Zulassungspopulation N=209 n (%)
	T N	Stadium	T N	Stadium	
Tumorbeschreibung in Kombination mit N2					
< 1 cm	T1 N2	IIIA	T1a N2	IIIA	1 (0,5 %)
> 1–2 cm	T1 N2	IIIA	T1b N2	IIIA	12 (5,7 %)
> 2–3 cm	T1 N2	IIIA	T1c N2	IIIA	8 (3,8 %)
> 3–4 cm, Infiltration der viszerale Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina, Tumore die zu einer partiellen Atelektasen oder Pneumonitis führen	T2a N2	IIIA	T2a N2	IIIA	22 (10,5 %)
> 4–5 cm, Infiltration der viszerale Pleura, des Hauptbronchus mit 2 cm oder mehr Abstand zu der Karina; Tumore die zu einer partiellen Atelektase oder Pneumonitis führen	T2a N2	IIIA	T2b N2	IIIA	10 (4,8 %)
> 5–7 cm	T2b N2	IIIA	T3 N2	IIIB	11 (5,3 %)
> 7cm	T3 N2	IIIA	T4 N2	IIIB	6 (2,9 %)
Infiltration der Brustwand, des Nervus phrenicus, der mediastinalen Pleura oder des parietalen Herzbeutels	T3 N2	IIIA	T3 N2	IIIB	6 (2,9 %)
Infiltration des Zwerchfells			T4 N2	IIIB	
Infiltration des Hauptbronchus mit < 2 cm Abstand zu der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore bis 4 cm			T2a N2	IIIA	
Infiltration des Hauptbronchus < 2 cm distal der Karina oder tumorbedingte komplette Atelektase oder Pneumonitis, Tumore 4–5 cm			T2b N2	IIIA	
Infiltration des Mediastinum, des Herz, der großen Gefäße, der Luftröhre, des Nervus laryngeus recurrence, der Speiseröhre, der Wirbelkörper oder der Karina; Tumore mit separatem Knoten im gleichen oder einem anderem ipsilateralen Lappen als dem primären	T4 N2	IIIB	T4 N2	IIIB	---

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Wirksamkeit

Time-to-Event (TTE) Analysen

Stratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Overall Survival
 MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
 STUDY: GO29527
 Time to Event Analysis (Efficacy)

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)												Atezolizumab vs. Best Supportive Care(BSC)													
		Patients				Patients with Event				Censored				Time to event				Patients				Patients with Event				Censored				Time to event				log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status							
All	n/a	106	100,0	15	14,2	91	85,8	NE	NE	NE	NE	NE	NE	NE	NE	103	100,0	30	29,1	73	70,9	38,9	27,8	NE	NE	NE	NE	0,0116	0,45	0,242	0,851	Convergence criterion (GCONV=1E-8) satisfied.							

* indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_eff_tte2.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_eff_tte2_str_OS_EGFRALKNOUK_SP263T3_ST23_IT_18APR2022_29527.xls
 20JUN2022 9:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Overall Survival

MODEL: Stratified Analysis by Sex, Histology, Tumor Stage

STUDY: GO29527

Time to Event Summary (Efficacy)

	Atezolizumab (N=106)		Best Supportive Care (BSC) (N=103)
Patients with event (%)	15 (14.2%)		30 (29.1%)
Earliest contributing event			
Death	15		30
Patients without event (%)	91 (85.8%)		73 (70.9%)
Time to event (months)			
Median	NE		NE
95% CI	NE		NE
25% and 75%-tile	NE		38.9 - NE
Range	0.2* - 69.1*		0.2* - 72.0*
Stratified Analysis			
p-value (log-rank)		0,0116	
Hazard Ratio		0,454	
95% CI		(0.242, 0.851)	
Unstratified Analysis			
p-value (log-rank)		0,0049	
Hazard Ratio		0,422	
95% CI		(0.227, 0.784)	
Time Point Analysis			
2 Years			
Patients remaining at risk	99		84
Event Free Rate (%)	98,04		86,78
95% CI	(95.35, 100.00)		(80.09, 93.48)
Difference in Event Free Rate		11,26	
95% CI		(4.04, 18.47)	

Vollständige Darstellung relevanter Ergebnisse

	Atezolizumab (N=106)		Best Supportive Care (BSC) (N=103)
p-value (Z-test)		0,0022	
3 Years			
Patients remaining at risk	90		75
Event Free Rate (%)	89,13		77,48
95% CI	(83.06, 95.19)		(69.20, 85.77)
Difference in Event Free Rate		11,64	
95% CI		(1.37, 21.91)	
p-value (Z-test)		0,0263	
5 Years			
Patients remaining at risk	13		8
Event Free Rate (%)	84,81		67,54
95% CI	(77.68, 91.93)		(57.54, 77.55)
Difference in Event Free Rate		17,27	
95% CI		(4.99, 29.55)	
p-value (Z-test)		0,0059	

Summaries of duration (median and percentiles) are Kaplan-Meier estimates. 95% CIs for the median are computed using the method of Brookmeyer and Crowley. Hazard ratios were estimated by Cox regression.

* Censored, NE = Not estimable.

Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ef_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ef_tte_str_OS_EGFRALKNOUK_SP263T3_ST23_IT_18APR2022_29527.xls
20JUN2022 9:48

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Wirksamkeit

Time-to-Event (TTE) Analysen

Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Efficacy)

		Atezolizumab (N=106)											Best Supportive Care(BSC) (N=103)											Atezolizumab vs. Best Supportive Care(BSC)								
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio			Interaction Test				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)	
All	n/a	106	100,0	15	14,2	91	85,8	NE	NE	NE	NE	NE	NE	103	100,0	30	29,1	73	70,9	38,9	27,8	NE	NE	NE	NE	0,0049	0,42	0,23	0,78	Convergence criterion (GCONV=1E-8) satisfied.		
Sex per eCRF	Male	84	79,2	11	13,1	73	86,9	NE	NE	NE	NE	NE	NE	73	70,9	20	27,4	53	72,6	33,4	26,1	NE	NE	NE	NE	0,0122	0,40	0,19	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,7340	
	Female	22	20,8	4	18,2	18	81,8	NE	25,7	NE	NE	NE	NE	30	29,1	10	33,3	20	66,7	41,1	24,6	NE	NE	43,5	NE	0,2586	0,52	0,16	1,65	Convergence criterion (GCONV=1E-8) satisfied.		
Age at Randomization	< 65	65	61,3	8	12,3	57	87,7	NE	NE	NE	NE	NE	NE	62	60,2	18	29,0	44	71,0	38,9	26,0	NE	NE	NE	NE	0,0168	0,38	0,16	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,6801	
	>= 65	41	38,7	7	17,1	34	82,9	NE	36,7	NE	NE	NE	NE	41	39,8	12	29,3	29	70,7	39,2	26,2	NE	NE	52,6	NE	0,1177	0,48	0,19	1,23	Convergence criterion (GCONV=1E-8) satisfied.		
Geographic Region	Asia Pacific and Australia	30	28,3	2	6,7	28	93,3	NE	NE	NE	NE	NE	NE	24	23,3	4	16,7	20	83,3	NE	39,2	NE	NE	NE	NE	0,2094	0,35	0,06	1,93	Convergence criterion (GCONV=1E-8) satisfied.	0,9313	
	Europe and Middle East	66	62,3	12	18,2	54	81,8	NE	36,7	NE	NE	NE	NE	68	66,0	23	33,8	45	66,2	27,8	22,5	NE	NE	NE	NE	0,0263	0,46	0,23	0,93	Convergence criterion (GCONV=1E-8) satisfied.		
	North America	10	9,4	1	10,0	9	90,0	NE	38,5	NE	NE	NE	NE	11	10,7	3	27,3	8	72,7	43,5	36,4	NE	NE	43,5	NE	0,3203	0,34	0,03	3,23	Convergence criterion (GCONV=1E-8) satisfied.		
Race/Ethnicity	White	71	67,0	11	15,5	60	84,5	NE	46,6	NE	NE	NE	NE	77	74,8	24	31,2	53	68,8	33,4	24,6	NE	NE	NE	NE	0,0169	0,43	0,21	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,6162	
	Asian	31	29,2	2	6,5	29	93,5	NE	NE	NE	NE	NE	NE	24	23,3	5	20,8	19	79,2	NE	36,4	NE	NE	NE	NE	0,0923	0,27	0,05	1,39	Convergence criterion (GCONV=1E-8) satisfied.		
	Others	2	1,9	1	50,0	1	50,0	38,5	38,5	NE	NE	38,5	NE	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	2	1,9	1	50,0	1	50,0	33,1	33,1	NE	NE	33,1	NE	2	1,9	1	50,0	1	50,0	26,2	26,2	NE	NE	26,2	NE	0,8084	0,71	0,04	11,79	Convergence criterion (GCONV=1E-8) satisfied.		

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)												Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank p-value	Hazard Ratio				Interaction Test p-value (likelihood ratio)
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median		Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	
Tumor stage per eCRF	IIA	31	29,2	5	16,1	26	83,9	NE	46,6	NE	NE	NE	NE	33	32,0	8	24,2	25	75,8	52,6	28,6	NE	NE	NE	NE	0,3356	0,58	0,19	1,78	Convergence criterion (GCONV=1E-8) satisfied.	0,2756
	IIB	27	25,5	5	18,5	22	81,5	NE	33,4	NE	NE	NE	NE	15	14,6	3	20,0	12	80,0	NE	30,8	NE	NE	NE	NE	0,8836	0,90	0,21	3,76	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	48	45,3	5	10,4	43	89,6	NE	NE	NE	NE	NE	NE	55	53,4	19	34,5	36	65,5	29,8	22,5	NE	NE	43,5	NE	0,0039	0,26	0,10	0,70	Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy Regimen before Randomization	Cisplatin/Vinorelbine	44	41,5	6	13,6	38	86,4	NE	46,6	NE	NE	NE	NE	36	35,0	10	27,8	26	72,2	39,2	30,8	NE	NE	NE	NE	0,1271	0,46	0,17	1,28	Convergence criterion (GCONV=1E-8) satisfied.	0,6625
	Cisplatin/Docetaxel	13	12,3	1	7,7	12	92,3	NE	NE	NE	NE	NE	NE	19	18,4	7	36,8	12	63,2	26,1	13,5	NE	NE	26,2	NE	0,0596	0,17	0,02	1,38	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Gemcitabine	20	18,9	3	15,0	17	85,0	NE	36,7	NE	NE	NE	NE	16	15,5	4	25,0	12	75,0	43,5	18,8	NE	NE	43,5	NE	0,3157	0,47	0,11	2,12	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Pemetrexed	29	27,4	5	17,2	24	82,8	NE	33,4	NE	NE	NE	NE	32	31,1	9	28,1	23	71,9	41,1	22,2	NE	NE	NE	NE	0,3152	0,58	0,19	1,72	Convergence criterion (GCONV=1E-8) satisfied.	
Histology per eCRF	Squamous	47	44,3	7	14,9	40	85,1	NE	38,5	NE	NE	NE	NE	45	43,7	10	22,2	35	77,8	NE	26,1	NE	NE	NE	NE	0,2568	0,58	0,22	1,51	Convergence criterion (GCONV=1E-8) satisfied.	0,4368
	Non-Squamous	59	55,7	8	13,6	51	86,4	NE	NE	NE	NE	NE	NE	58	56,3	20	34,5	38	65,5	36,4	22,2	NE	NE	52,6	NE	0,0081	0,35	0,15	0,79	Convergence criterion (GCONV=1E-8) satisfied.	
Smoking History	Never	11	10,4	2	18,2	9	81,8	NE	16,9	NE	NE	NE	NE	9	8,7	3	33,3	6	66,7	34,5	22,5	NE	NE	27,8	NE	0,4038	0,47	0,08	2,84	Convergence criterion (GCONV=1E-8) satisfied.	0,6421
	Previous	79	74,5	9	11,4	70	88,6	NE	NE	NE	NE	NE	NE	73	70,9	20	27,4	53	72,6	39,2	26,1	NE	NE	NE	NE	0,0076	0,36	0,16	0,79	Convergence criterion (GCONV=1E-8) satisfied.	
	Current	16	15,1	4	25,0	12	75,0	36,7	25,7	NE	NE	NE	NE	21	20,4	7	33,3	14	66,7	38,9	23,6	NE	NE	38,9	NE	0,6228	0,74	0,21	2,52	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG Status	0	66	62,3	8	12,1	58	87,9	NE	NE	NE	NE	NE	NE	53	51,5	13	24,5	40	75,5	41,1	29,8	NE	NE	NE	NE	0,0541	0,43	0,18	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,9452

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=106)												Best Supportive Care (BSC) (N=103)												Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	1 and 2 combined	40	37,7	7	17,5	33	82,5	NE	36,7	NE	NE	NE	NE	50	48,5	17	34,0	33	66,0	33,7	22,5	NE	NE	52,6	NE	0,0743	0,46	0,19	1,10	Convergence criterion (GCONV=1E-8) satisfied.	
Regional Lymph Node Stage (pN)	N0	30	28,3	5	16,7	25	83,3	NE	33,4	NE	NE	NE	NE	20	19,4	5	25,0	15	75,0	43,5	36,4	NE	NE	NE	NE	0,5659	0,70	0,20	2,41	Convergence criterion (GCONV=1E-8) satisfied.	0,6363
	N1	39	36,8	5	12,8	34	87,2	NE	46,6	NE	NE	NE	NE	43	41,7	11	25,6	32	74,4	41,1	28,6	NE	NE	NE	NE	0,0924	0,42	0,14	1,20	Convergence criterion (GCONV=1E-8) satisfied.	
	N2	37	34,9	5	13,5	32	86,5	NE	33,4	NE	NE	NE	NE	40	38,8	14	35,0	26	65,0	26,2	22,2	NE	NE	36,4	NE	0,0264	0,33	0,12	0,92	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
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 20JUN2022 9:44

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

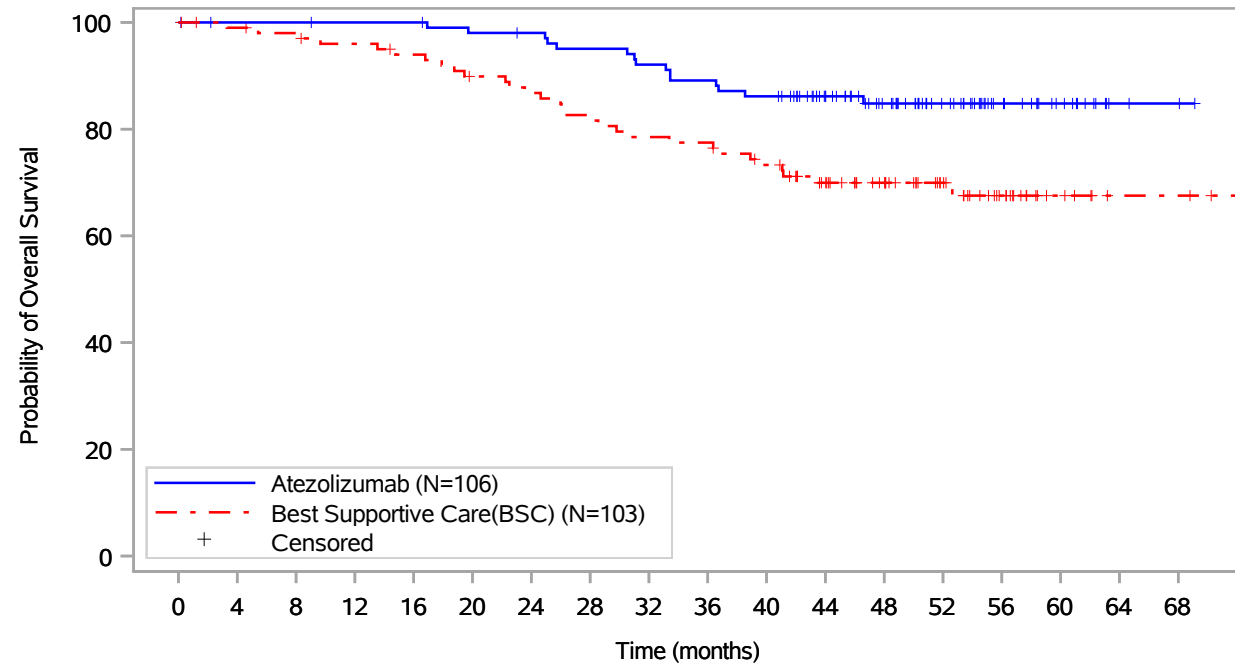
Wirksamkeit

KM Plots

Stratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Overall Survival
STUDY: GO29527



Patients at risk		0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68
Atezolizumab (N=106)		106	104	104	103	103	100	99	96	93	90	87	72	58	39	22	13	3	2
Best Supportive Care(BSC) (N=103)		103	100	98	95	92	87	84	79	76	75	69	56	45	31	19	8	3	3
Patients censored		0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68
Atezolizumab (N=106)		0	2	2	3	3	4	5	5	5	5	5	20	33	52	69	78	88	89
Best Supportive Care(BSC) (N=103)		0	2	3	4	5	6	6	6	6	6	8	18	29	43	54	65	70	70

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 20JUN2022 9:47

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Generelle Verträglichkeit

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	99	95,2	5	4,8	101	100,0	71	70,3	30	29,7	<.0001	2,46	1,80	3,37	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	77	93,9	5	6,1	71	70,3	46	64,8	25	35,2	<.0001	2,74	1,88	4,01	Convergence criterion (GCONV=1E-8) satisfied.	0,3855
	Female	22	21,2	22	100,0	0	0,0	30	29,7	25	83,3	5	16,7	0,0154	2,05	1,13	3,70	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	59	92,2	5	7,8	62	61,4	41	66,1	21	33,9	<.0001	2,69	1,79	4,05	Convergence criterion (GCONV=1E-8) satisfied.	0,4994
	>= 65	40	38,5	40	100,0	0	0,0	39	38,6	30	76,9	9	23,1	0,0015	2,22	1,34	3,68	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	28	96,6	1	3,4	23	22,8	16	69,6	7	30,4	0,0049	2,41	1,28	4,51	Convergence criterion (GCONV=1E-8) satisfied.	0,9777
	Europe and Middle East	65	62,5	61	93,8	4	6,2	68	67,3	47	69,1	21	30,9	<.0001	2,41	1,63	3,57	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	10	100,0	0	0,0	10	9,9	8	80,0	2	20,0	0,0579	2,53	0,94	6,83	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Tumor stage per eCRF	IIA	31	29,8	31	100,0	0	0,0	33	32,7	23	69,7	10	30,3	<.0001	3,11	1,74	5,55	Convergence criterion (GCONV=1E-8) satisfied.	0,6635
	IIB	27	26,0	26	96,3	1	3,7	15	14,9	12	80,0	3	20,0	0,0389	2,09	1,03	4,27	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	42	91,3	4	8,7	53	52,5	36	67,9	17	32,1	0,0003	2,26	1,43	3,56	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
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 27JUN2022 14:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	21	20,2	83	79,8	101	100,0	11	10,9	90	89,1	0,0624	1,98	0,95	4,10	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	16	19,5	66	80,5	71	70,3	6	8,5	65	91,5	0,0553	2,43	0,95	6,22	Convergence criterion (GCONV=1E-8) satisfied.	0,5501
	Female	22	21,2	5	22,7	17	77,3	30	29,7	5	16,7	25	83,3	0,5220	1,50	0,43	5,17	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	13	20,3	51	79,7	62	61,4	9	14,5	53	85,5	0,3685	1,47	0,63	3,45	Convergence criterion (GCONV=1E-8) satisfied.	0,2228
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	2	5,1	37	94,9	0,0481	4,21	0,89	19,82	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	3	13,0	20	87,0	0,2259	2,22	0,59	8,38	Convergence criterion (GCONV=1E-8) satisfied.	0,9520

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	7	10,3	61	89,7	0,2471	1,74	0,67	4,48	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5153	2,18	0,20	24,02	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	3	9,1	30	90,9	0,6087	1,47	0,33	6,59	Convergence criterion (GCONV=1E-8) satisfied.	0,6607
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9374	1,10	0,10	12,15	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	15	32,6	31	67,4	53	52,5	7	13,2	46	86,8	0,0168	2,85	1,16	7,00	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

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27JUN2022 14:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	20	19,2	84	80,8	101	100,0	9	8,9	92	91,1	0,0346	2,28	1,04	5,01	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	15	18,3	67	81,7	71	70,3	6	8,5	65	91,5	0,0839	2,25	0,87	5,81	Convergence criterion (GCONV=1E-8) satisfied.	0,8931
	Female	22	21,2	5	22,7	17	77,3	30	29,7	3	10,0	27	90,0	0,2003	2,47	0,59	10,35	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	12	18,8	52	81,3	62	61,4	8	12,9	54	87,1	0,3469	1,53	0,63	3,75	Convergence criterion (GCONV=1E-8) satisfied.	0,0961
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	1	2,6	38	97,4	0,0190	8,07	1,01	64,52	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	7	24,1	22	75,9	23	22,8	3	13,0	20	87,0	0,3456	1,90	0,49	7,33	Convergence criterion (GCONV=1E-8) satisfied.	0,9589

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	5	7,4	63	92,6	0,0880	2,44	0,85	7,01	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5153	2,18	0,20	24,02	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	2	6,1	31	93,9	0,3490	2,20	0,40	12,03	Convergence criterion (GCONV=1E-8) satisfied.	0,7482
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9374	1,10	0,10	12,15	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	14	30,4	32	69,6	53	52,5	6	11,3	47	88,7	0,0167	3,04	1,17	7,92	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 14:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
All	n/a	104	100,0	4	3,8	100	96,2	101	100,0	3	3,0	98	97,0	0,6784	1,37	0,31	6,13	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2209	3,60	0,40	32,18	Convergence criterion (GCONV=1E-8) satisfied.	0,0619
	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2559	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9830	1,02	0,14	7,26	Convergence criterion (GCONV=1E-8) satisfied.	0,6755
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5155	2,17	0,20	23,98	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	1	4,3	22	95,7	0,3924	2,59	0,27	24,94	Convergence criterion (GCONV=1E-8) satisfied.	0,6172

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6193	0,55	0,05	6,06	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	2	6,1	31	93,9	0,6206	0,55	0,05	6,07	Convergence criterion (GCONV=1E-8) satisfied.	0,4957
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2063	3,87	0,40	37,26	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	\geq 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	16	15,4	88	84,6	101	100,0	4	4,0	97	96,0	0,0057	4,15	1,39	12,42	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	12	14,6	70	85,4	71	70,3	4	5,6	67	94,4	0,0712	2,72	0,88	8,43	Convergence criterion (GCONV=1E-8) satisfied.	0,0831
	Female	22	21,2	4	18,2	18	81,8	30	29,7	0	0,0	30	100,0	0,0154	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	8	12,5	56	87,5	62	61,4	3	4,8	59	95,2	0,1150	2,78	0,74	10,48	Convergence criterion (GCONV=1E-8) satisfied.	0,3649
	\geq 65	40	38,5	8	20,0	32	80,0	39	38,6	1	2,6	38	97,4	0,0183	8,15	1,02	65,14	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	5	17,2	24	82,8	23	22,8	2	8,7	21	91,3	0,3566	2,12	0,41	10,95	Convergence criterion (GCONV=1E-8) satisfied.	0,5562

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	10	15,4	55	84,6	68	67,3	2	2,9	66	97,1	0,0126	5,56	1,22	25,36	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	4	12,9	27	87,1	33	32,7	2	6,1	31	93,9	0,3269	2,28	0,42	12,47	Convergence criterion (GCONV=1E-8) satisfied.	0,5440
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2767	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	10	21,7	36	78,3	53	52,5	2	3,8	51	96,2	0,0066	6,27	1,37	28,62	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 14:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	20	19,2	84	80,8	101	100,0	0	0	101	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	17	20,7	65	79,3	71	70,3	0	0	71	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0	30	100,0	0,0433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	12	18,8	52	81,3	62	61,4	0	0	62	100,0	0,0004	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9977
	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	0	0	39	100,0	0,0040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	0	0	23	100,0	0,0088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	0	0	68	100,0	0,0006	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	7	22,6	24	77,4	33	32,7	0	0	33	100,0	0,0047	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0	15	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	11	23,9	35	76,1	53	52,5	0	0	53	100,0	0,0002	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTWDAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

27JUN2022 14:36

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

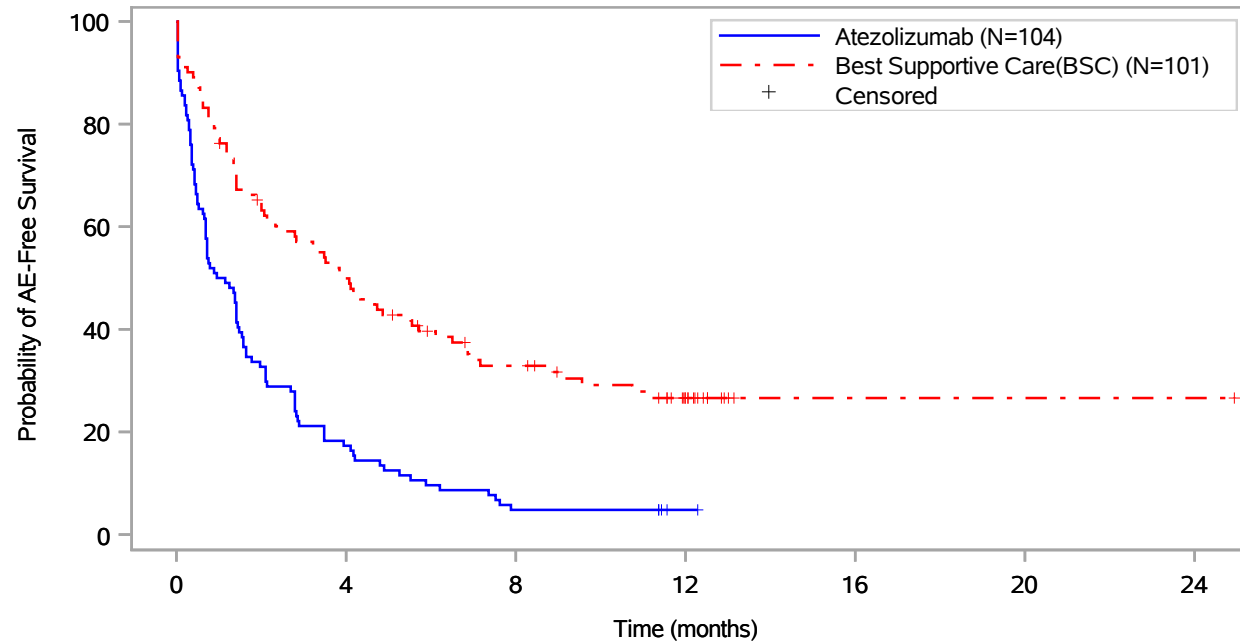
Generelle Verträglichkeit

KM Plots

Unstratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527



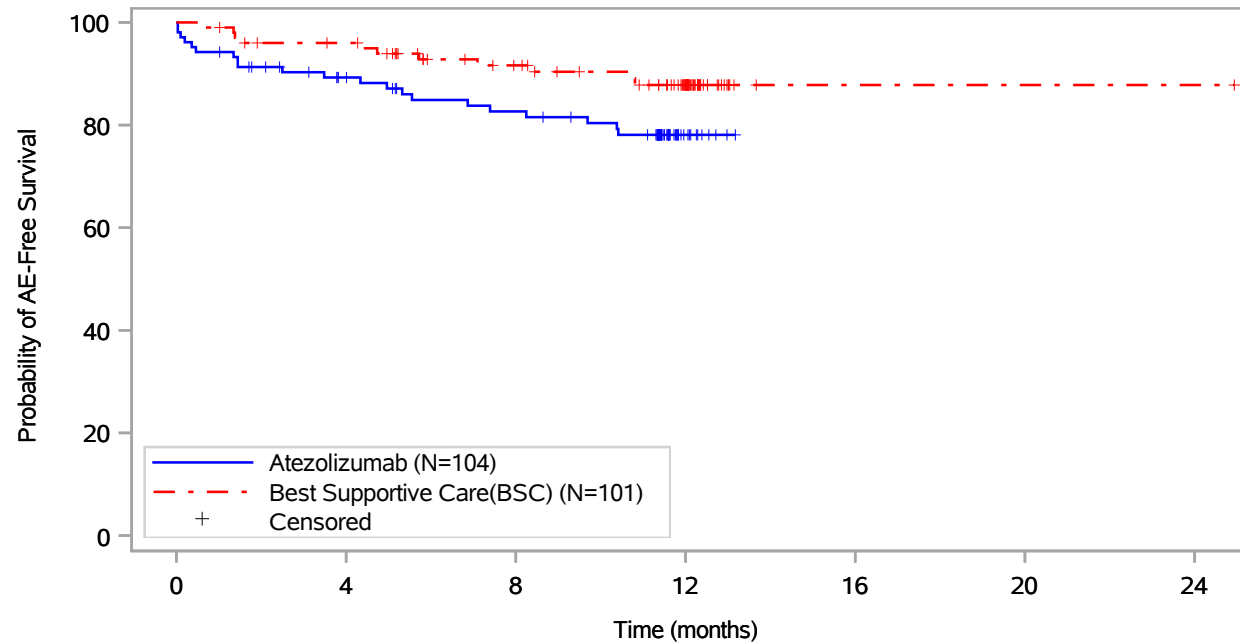
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	18	5	1	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	49	29	13	1	1	1	1
Patients censored								
Atezolizumab (N=104)	0	0	0	4	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	2	6	17	29	29	29	29

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..sis/ACE_OS_IA/prod/output/g_km_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527



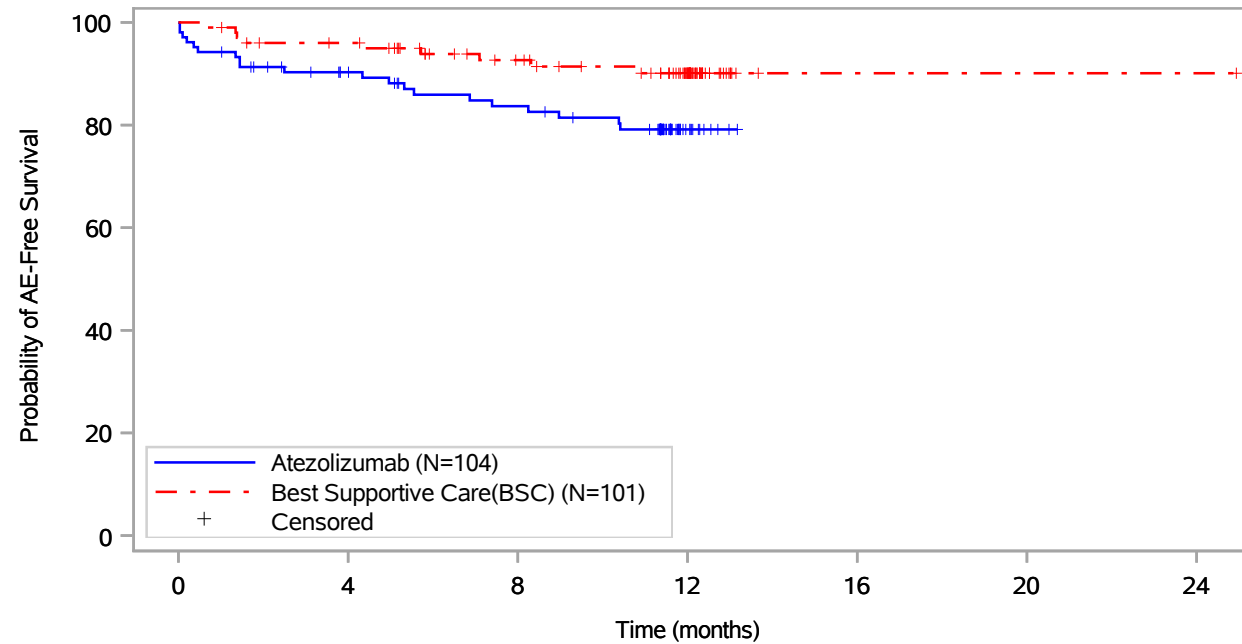
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	84	74	10	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	93	76	49	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	9	13	73	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	41	89	89	89

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527



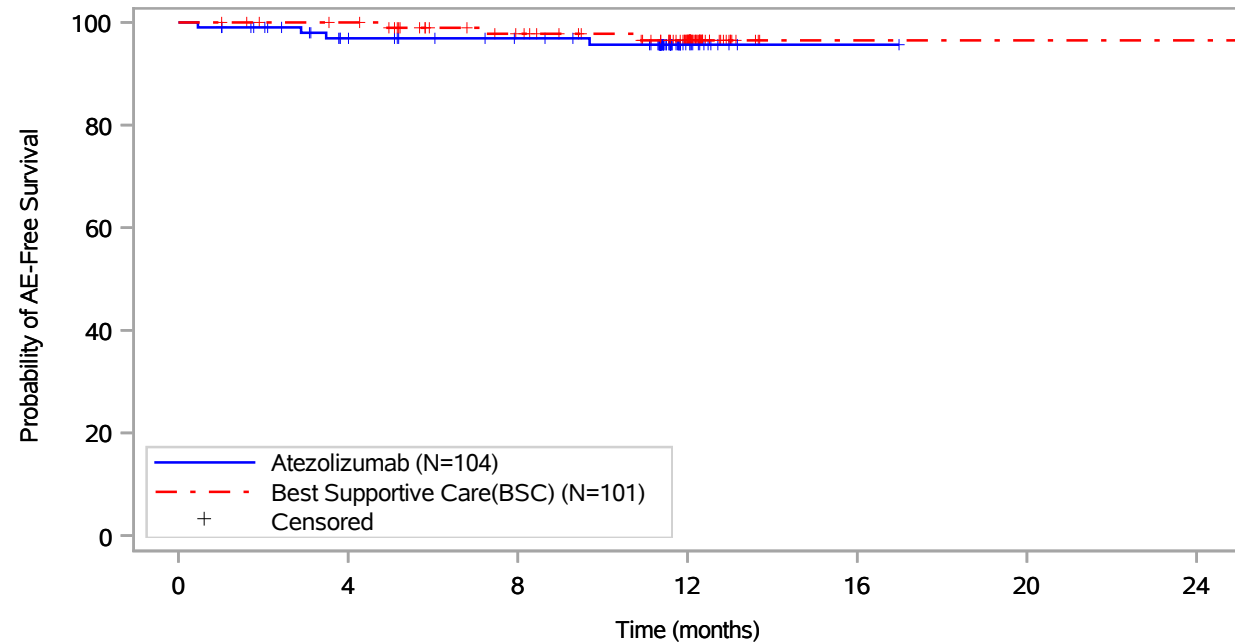
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	85	75	11	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	93	76	49	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	9	13	73	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	43	91	91	91	91

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:13

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527



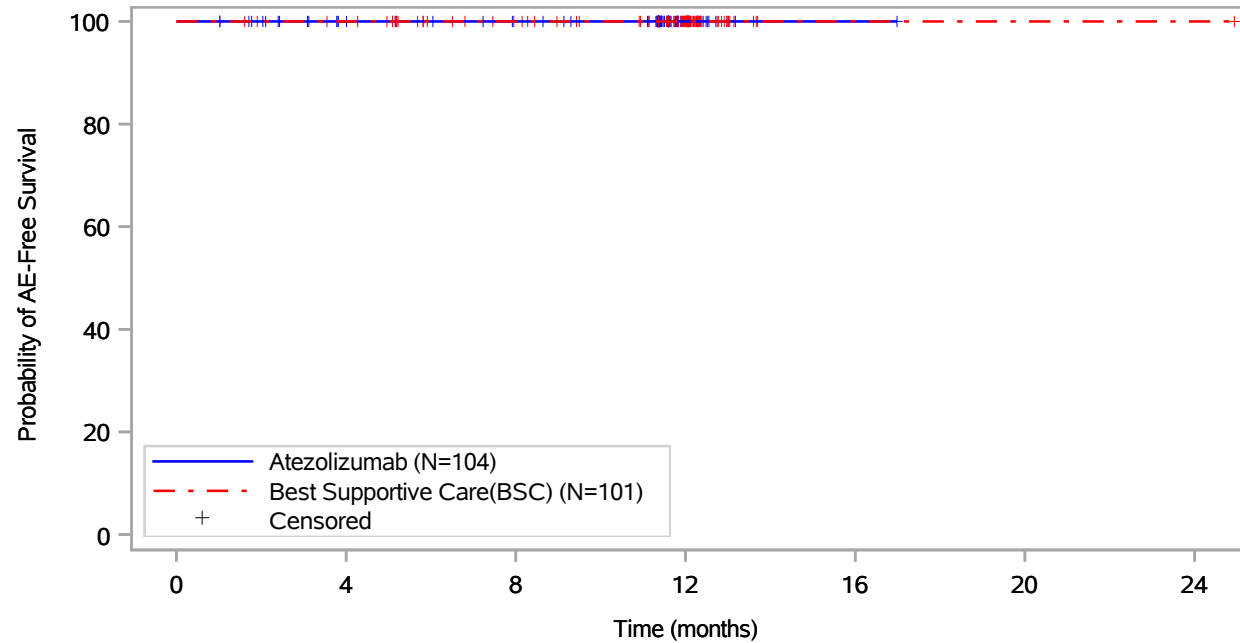
Patients at risk							
Atezolizumab (N=104)	104	87	80	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	87	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	97	97	97

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 5 Adverse Event
STUDY: GO29527



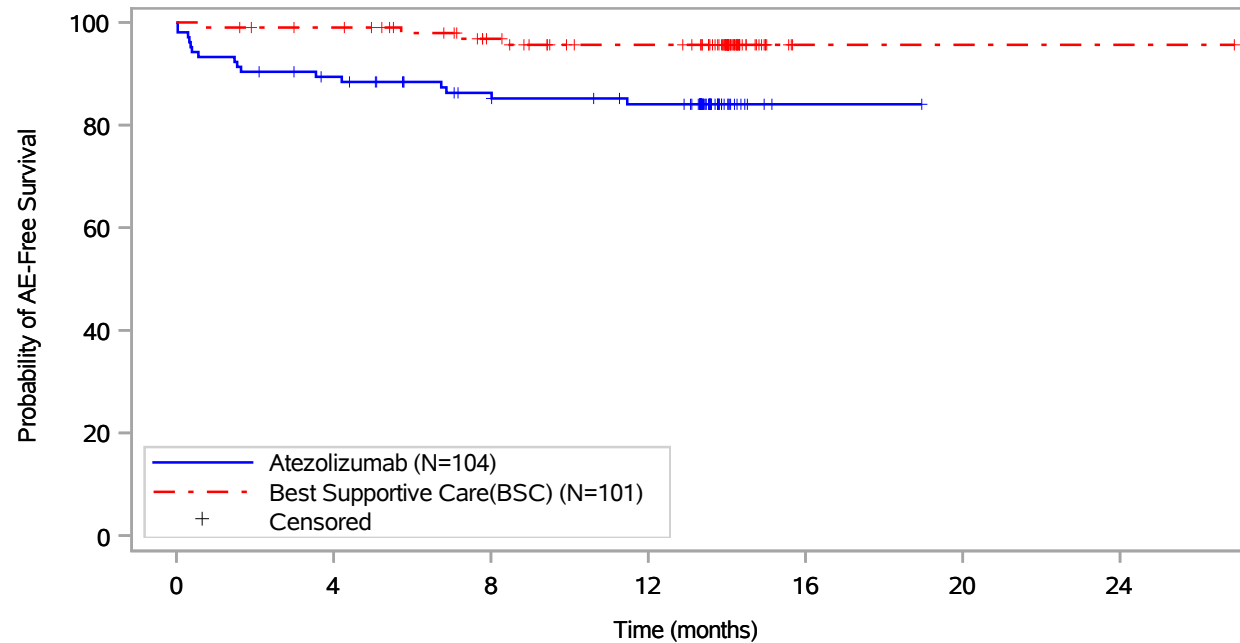
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:16

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527



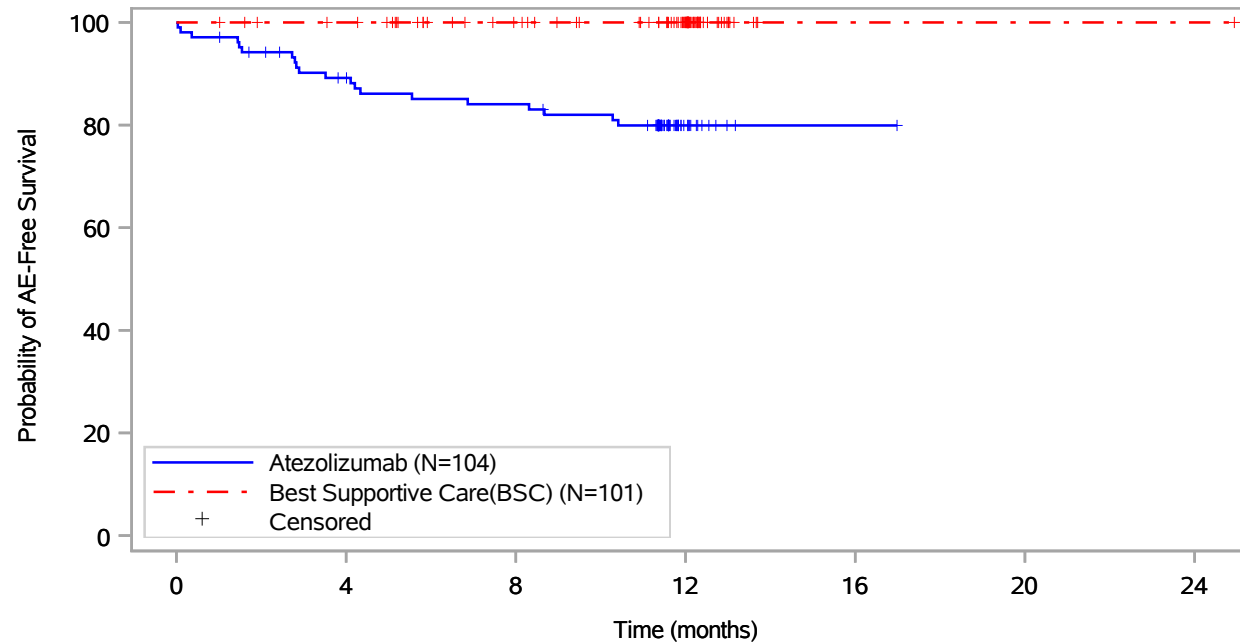
Patients at risk							
Atezolizumab (N=104)	104	90	79	74	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	73	1	1	1
Patients censored							
Atezolizumab (N=104)	0	3	11	14	87	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	96	96	96

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..\ACE_OS_IA\prod\output\g_km_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event leading to Atezolizumab Discontinuation
STUDY: GO29527



Patients at risk							
Atezolizumab (N=104)	104	88	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	5	6	71	83	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 15:19

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Generelle Verträglichkeit

Outcome

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: All Patients

MODEL: --

STUDY: GO29527

Outcome of Adverse Events

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care(BSC) (N=101)															
	Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	576	423	73,4	8	1,4	127	22,0	0	0,0	15	2,6	3	0,5	0	0,0	232	163	70,3	1	0,4	63	27,2	0	0,0	4	1,7	1	0,4	0	0,0
Grade 1	360	275	76,4	4	1,1	72	20,0	0	0,0	8	2,2	1	0,3	0	0,0	133	99	74,4	0	0,0	34	25,6	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	178	115	64,6	3	1,7	52	29,2	0	0,0	6	3,4	2	1,1	0	0,0	83	54	65,1	1	1,2	25	30,1	0	0,0	2	2,4	1	1,2	0	0,0
Grade 3	34	29	85,3	1	2,9	3	8,8	0	0,0	1	2,9	0	0,0	0	0,0	13	8	61,5	0	0,0	3	23,1	0	0,0	2	15,4	0	0,0	0	0,0
Grade 4	4	4	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	3	2	66,7	0	0,0	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0
Any SAEs																														
All	22	19	86,4	1	4,5	1	4,5	0	0,0	0	0,0	1	4,5	0	0,0	7	5	71,4	0	0,0	1	14,3	0	0,0	1	14,3	0	0,0	0	0,0
Grade 1	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	9	7	77,8	1	11,1	0	0,0	0	0,0	0	0,0	1	11,1	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	8	7	87,5	0	0,0	1	12,5	0	0,0	0	0,0	0	0,0	0	0,0	5	4	80,0	0	0,0	0	0,0	0	0,0	1	20,0	0	0,0	0	0,0
Grade 4	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0
AEs leading to Atezolizumab discontinuation																														
All	21	16	76,2	0	0,0	4	19,0	0	0,0	0	0,0	1	4,8	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	3	37,5	0	0,0	4	50,0	0	0,0	0	0,0	1	12,5	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	10	10	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Vollständige Darstellung relevanter Ergebnisse

	Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)															
	Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED /RESOLVED		RECOVERED WITH SEQUELAE		NOT RECOVERED /NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_resolved.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_resolved_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 14:23

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		n/a	104	100,0	12	11,5	92	88,5	101	100,0	7	6,9	94	93,1	0,2060	1,81	0,71	4,60	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Anaemia	n/a	104	100,0	8	7,7	96	92,3	101	100,0	7	6,9	94	93,1	0,7495	1,18	0,43	3,25	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Lymphadenopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9935	1,01	0,06	16,18	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Sarcoidosis of lymph node	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Thrombocytopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		n/a	104	100,0	6	5,8	98	94,2	101	100,0	0	0,0	101	100,0	0,0113	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1498	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Cardiac failure	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Cardiac failure chronic	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Metabolic cardiomyopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Palpitations	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Sinus bradycardia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Congenital, familial and genetic disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3047	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Congenital, familial and genetic disorders	Gilbert's syndrome	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3047	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4040	0,49	0,09	2,69	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Ear discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Tinnitus	n/a	104	100,0	0	0,0	104	100,0	101	100,0	3	3,0	98	97,0	0,0800	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Vertigo	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Ear and labyrinth disorders	Vestibular ataxia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders		n/a	104	100,0	17	16,3	87	83,7	101	100,0	2	2,0	99	98,0	0,0002	9,53	2,20	41,31	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Autoimmune thyroiditis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Hyperthyroidism	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2374	2,59	0,50	13,39	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Hypothyroidism	n/a	104	100,0	11	10,6	93	89,4	101	100,0	0	0,0	101	100,0	0,0005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders		n/a	104	100,0	7	6,7	97	93,3	101	100,0	5	5,0	96	95,0	0,5136	1,46	0,46	4,61	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Blepharitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5510	0,49	0,04	5,40	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Dry eye	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Eyelid oedema	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Ocular discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Retinal detachment	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vision blurred	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1459	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Visual impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous floaters	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders		n/a	104	100,0	23	22,1	81	77,9	101	100,0	12	11,9	89	88,1	0,0370	2,07	1,03	4,17	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal distension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal hernia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain lower	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal pain upper	n/a	104	100,0	1	1,0	103	99,0	101	100,0	3	3,0	98	97,0	0,3154	0,33	0,03	3,19	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Bowel movement irregularity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Cheilitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Constipation	n/a	104	100,0	6	5,8	98	94,2	101	100,0	1	1,0	100	99,0	0,0453	6,57	0,79	54,88	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Diarrhoea	n/a	104	100,0	7	6,7	97	93,3	101	100,0	0	0,0	101	100,0	0,0068	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dry mouth	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0765	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dyspepsia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Dysphagia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Faeces soft	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Flatulence	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9693	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Haemorrhoids	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9880	1,02	0,06	16,33	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Hyperaesthesia teeth	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Large intestine polyp	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Mouth ulceration	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Nausea	n/a	104	100,0	7	6,7	97	93,3	101	100,0	2	2,0	99	98,0	0,0884	3,59	0,75	17,28	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Stomatitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Toothache	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Vomiting	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5293	2,13	0,19	23,54	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions		n/a	104	100,0	25	24,0	79	76,0	101	100,0	12	11,9	89	88,1	0,0163	2,27	1,14	4,53	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Asthenia	n/a	104	100,0	9	8,7	95	91,3	101	100,0	2	2,0	99	98,0	0,0310	4,63	1,00	21,44	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Catheter site haematoma	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Chest discomfort	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Chest pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1578	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chills	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3045	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Fatigue	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6599	1,49	0,25	8,92	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Gait disturbance	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1587	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	3	3,0	98	97,0	0,0864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Oedema	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Oedema peripheral	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3061	3,07	0,32	29,54	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Peripheral swelling	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Pyrexia	n/a	104	100,0	11	10,6	93	89,4	101	100,0	0	0,0	101	100,0	0,0008	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	1	1,0	100	99,0	0,0875	5,32	0,62	45,50	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic steatosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9664	1,06	0,07	16,98	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hyperbilirubin aemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2988	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0833	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0833	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	45	43,3	59	56,7	101	100,0	35	34,7	66	65,3	0,0619	1,52	0,98	2,37	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Bronchitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	4	4,0	97	96,0	0,1804	0,25	0,03	2,24	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Candida infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Conjunctivitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cystitis	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,2329	3,68	0,37	36,14	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Empyema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3258	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Fungal pharyngitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Furuncle	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Gastroenteritis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Gastrointestinal bacterial overgrowth	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Herpes zoster	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Infectious pleural effusion	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Influenza	n/a	104	100,0	3	2,9	101	97,1	101	100,0	3	3,0	98	97,0	0,9866	1,01	0,20	5,02	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Laryngitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Nasopharyngitis	n/a	104	100,0	8	7,7	96	92,3	101	100,0	13	12,9	88	87,1	0,3060	0,63	0,26	1,53	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Oral fungal infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Oral herpes	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Otitis externa	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Otitis media	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Paronychia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pharyngitis	n/a	104	100,0	3	2,9	101	97,1	101	100,0	3	3,0	98	97,0	0,9982	1,00	0,20	4,96	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	1	1,0	100	99,0	0,1739	4,07	0,45	36,40	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia pneumococcal	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Prostate infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pulpitis dental	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Respiratory tract infection	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6170	1,57	0,26	9,42	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Respiratory tract infection viral	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1515	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Rhinitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1586	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Sepsis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Sinusitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1574	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Skin infection	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tinea infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tonsillitis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tooth abscess	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3230	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tooth infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tracheitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Upper respiratory tract infection	n/a	104	100,0	3	2,9	101	97,1	101	100,0	5	5,0	96	95,0	0,5071	0,62	0,15	2,59	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Urinary tract infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,6007	0,53	0,05	5,87	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Vaginal infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Viral infection	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1566	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Viral upper respiratory tract infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications		n/a	104	100,0	7	6,7	97	93,3	101	100,0	4	4,0	97	96,0	0,3379	1,81	0,53	6,18	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Contusion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Eye contusion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Fall	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5532	2,04	0,18	22,46	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fracture	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Joint dislocation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Ligament sprain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9960	1,01	0,06	16,11	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Limb injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Rib fracture	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Injury, poisoning and procedural complications	Vascular access site pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		n/a	104	100,0	34	32,7	70	67,3	101	100,0	9	8,9	92	91,1	<.0001	4,46	2,13	9,32	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	8	7,7	96	92,3	101	100,0	3	3,0	98	97,0	0,1303	2,68	0,71	10,09	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	5	4,8	99	95,2	101	100,0	3	3,0	98	97,0	0,4791	1,67	0,40	6,98	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood alkaline phosphatase increased	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood bilirubin increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood cholesterol increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatinine increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatine phosphokinase increased	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0826	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood creatinine increased	n/a	104	100,0	9	8,7	95	91,3	101	100,0	1	1,0	100	99,0	0,0080	9,71	1,23	76,70	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood iron decreased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1658	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood lactate dehydrogenase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood magnesium decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3299	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood pressure increased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3326	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood thyroid stimulating hormone decreased	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0388	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood triglycerides increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Blood uric acid increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5755	1,96	0,18	21,62	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Creatinine renal clearance decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9908	1,02	0,06	16,26	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Gastric pH decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	International normalised ratio increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Liver function test increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5574	0,49	0,04	5,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Oxygen saturation decreased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Transaminases increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Urine bilirubin increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight decreased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,0664	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight increased	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2246	2,66	0,52	13,70	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		n/a	104	100,0	20	19,2	84	80,8	101	100,0	12	11,9	89	88,1	0,1457	1,69	0,83	3,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Decreased appetite	n/a	104	100,0	4	3,8	100	96,2	101	100,0	1	1,0	100	99,0	0,1900	3,89	0,43	34,81	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Dehydration	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1599	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypercholesterolaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1633	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperglycaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9999	1,00	0,14	7,10	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5704	1,98	0,18	21,80	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperuricaemia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5719	1,97	0,18	21,75	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypoglycaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0423	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypomagnesaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3409	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphataemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9917	0,99	0,06	15,76	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypovolaemia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Iron deficiency	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Vitamin D deficiency	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders		n/a	104	100,0	31	29,8	73	70,2	101	100,0	17	16,8	84	83,2	0,0121	2,10	1,16	3,81	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	104	100,0	13	12,5	91	87,5	101	100,0	5	5,0	96	95,0	0,0404	2,81	1,00	7,88	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9986	1,00	0,06	15,95	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Back pain	n/a	104	100,0	4	3,8	100	96,2	101	100,0	5	5,0	96	95,0	0,8604	0,89	0,24	3,35	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Bone pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9898	1,02	0,06	16,28	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Coccydynia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9882	1,02	0,06	16,33	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Limb discomfort	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscle fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0455	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	4	3,8	100	96,2	101	100,0	2	2,0	99	98,0	0,4014	2,04	0,37	11,13	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Neck pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3198	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Pain in extremity	n/a	104	100,0	4	3,8	100	96,2	101	100,0	3	3,0	98	97,0	0,6815	1,37	0,31	6,11	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Periarthritis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3409	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Spinal pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Synovial cyst	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Tendonitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	5	4,8	99	95,2	101	100,0	4	4,0	97	96,0	0,6688	1,33	0,36	4,99	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3113	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		n/a	104	100,0	26	25,0	78	75,0	101	100,0	23	22,8	78	77,2	0,5758	1,17	0,67	2,06	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Arachnoid cyst	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral arteriosclerosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral infarction	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3116	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cognitive disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Disturbance in attention	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dizziness	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2368	2,59	0,50	13,38	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Dysaesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Encephalopathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Headache	n/a	104	100,0	5	4,8	99	95,2	101	100,0	5	5,0	96	95,0	0,9516	1,04	0,30	3,59	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Hypoaesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1532	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Lethargy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Loss of consciousness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Memory impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Migraine	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Myelopathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Neuropathy peripheral	n/a	104	100,0	6	5,8	98	94,2	101	100,0	1	1,0	100	99,0	0,0522	6,24	0,75	51,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Neurotoxicity	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4347	0,51	0,09	2,81	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Parosmia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3022	3,10	0,32	29,78	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Polyneuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1650	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Seizure	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Somnolence	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9862	0,98	0,06	15,60	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9847	0,97	0,06	15,56	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Tension headache	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3223	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Transient ischaemic attack	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Upper motor neurone lesion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3232	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Vocal cord paralysis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders		n/a	104	100,0	7	6,7	97	93,3	101	100,0	5	5,0	96	95,0	0,4238	1,60	0,50	5,09	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Anxiety	n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0,0	101	100,0	0,0103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Depressed mood	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Depression	n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9522	1,06	0,15	7,54	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Insomnia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1469	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Mental status changes	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Psychiatric symptom	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3326	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Psychiatric disorders	Sleep disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	6	5,8	98	94,2	101	100,0	4	4,0	97	96,0	0,4953	1,55	0,44	5,49	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Acute kidney injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1460	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Dysuria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9722	1,05	0,07	16,81	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Micturition disorder	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Pollakiuria	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Proteinuria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Renal cyst	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Renal impairment	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Urinary tract pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6601	1,49	0,25	8,92	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Balanoposthitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3113	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast discharge	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Breast pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Gynaecomastia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	31	29,8	73	70,2	101	100,0	20	19,8	81	80,2	0,0529	1,74	0,99	3,09	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Catarrh	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3381	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Cough	n/a	104	100,0	15	14,4	89	85,6	101	100,0	10	9,9	91	90,1	0,2644	1,58	0,70	3,53	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dysphonia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	8	7,7	96	92,3	101	100,0	5	5,0	96	95,0	0,2853	1,84	0,59	5,75	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Haemoptysis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1541	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Laryngospasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Lung disorder	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6250	1,56	0,26	9,32	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pleurisy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0143	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Productive cough	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0382	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rales	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1517	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0430	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3300	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	36	34,6	68	65,4	101	100,0	6	5,9	95	94,1	<.0001	7,32	3,08	17,39	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Actinic keratosis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3299	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Alopecia	n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6481	1,51	0,25	9,05	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3301	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dermatitis acneiform	n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0771	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2965	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Drug eruption	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Dry skin	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0378	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Erythema	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1565	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Miliaria	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3338	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Onychoclasia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Papule	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Pruritus	n/a	104	100,0	12	11,5	92	88,5	101	100,0	2	2,0	99	98,0	0,0046	6,53	1,46	29,18	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Psoriasis	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1427	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	8	7,7	96	92,3	101	100,0	0	0,0	101	100,0	0,0042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash erythematous	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash maculo-papular	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash pruritic	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3116	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Scar pain	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Skin burning sensation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3072	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Toxic skin eruption	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Urticaria	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Vitiligo	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Surgical and medical procedures		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Surgical and medical procedures	Cancer surgery	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	5	5,0	96	95,0	0,9552	1,04	0,30	3,58	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hot flush	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	4	3,8	100	96,2	101	100,0	0	0,0	101	100,0	0,0394	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypotension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Orthostatic hypotension	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Phlebitis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Phlebitis superficial	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Vascular stenosis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3149	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 17:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Male	82	78,8	8	9,8	74	90,2	71	70,3	5	7,0	66	93,0	0,4818	1,49	0,49	4,56	Convergence criterion (GCONV=1E-8) satisfied.	0,4367
Blood and lymphatic system disorders		Female	22	21,2	4	18,2	18	81,8	30	29,7	2	6,7	28	93,3	0,1738	3,08	0,56	16,94	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	Male	82	78,8	5	6,1	77	93,9	71	70,3	5	7,0	66	93,0	0,8796	0,91	0,26	3,14	Convergence criterion (GCONV=1E-8) satisfied.	0,3849
Blood and lymphatic system disorders	Anaemia	Female	22	21,2	3	13,6	19	86,4	30	29,7	2	6,7	28	93,3	0,3624	2,26	0,37	13,64	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Lymphadenopathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1289
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		Male	82	78,8	6	7,3	76	92,7	71	70,3	0	0,0	71	100,0	0,0179	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Cardiac disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Atrial fibrillation	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Cardiac failure	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Cardiac failure chronic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Metabolic cardiomyopathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Palpitations	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3552	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Sinus bradycardia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2756	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Congenital, familial and genetic disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2756	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Congenital, familial and genetic disorders	Gilbert's syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2523
Ear and labyrinth disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9894	0,99	0,16	5,92	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Ear discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Ear and labyrinth disorders	Ear discomfort	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Ear and labyrinth disorders	Tinnitus	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2424	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Ear and labyrinth disorders	Vertigo	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Ear and labyrinth disorders	Vestibular ataxia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Male	82	78,8	15	18,3	67	81,7	71	70,3	1	1,4	70	98,6	0,0005	14,76	1,95	111,87	Convergence criterion (GCONV=1E-8) satisfied.	0,3458

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2873	3,41	0,31	37,61	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Autoimmune thyroiditis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2225	3,59	0,40	32,17	Convergence criterion (GCONV=1E-8) satisfied.	0,6272
Endocrine disorders	Hyperthyroidism	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7143	1,67	0,10	26,72	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	Male	82	78,8	10	12,2	72	87,8	71	70,3	0	0,0	71	100,0	0,0020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Endocrine disorders	Hypothyroidism	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	4	5,6	67	94,4	0,8645	1,12	0,30	4,18	Convergence criterion (GCONV=1E-8) satisfied.	0,4438
Eye disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2789	3,47	0,31	38,36	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Eye disorders	Blepharitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4843	0,44	0,04	4,80	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Dry eye	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Eyelid oedema	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Eye disorders	Ocular discomfort	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Retinal detachment	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1769	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Eye disorders	Vision blurred	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Visual impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous floaters	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous floaters	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	17	20,7	65	79,3	71	70,3	7	9,9	64	90,1	0,0489	2,36	0,98	5,70	Convergence criterion (GCONV=1E-8) satisfied.	0,7885
Gastrointestinal disorders		Female	22	21,2	6	27,3	16	72,7	30	29,7	5	16,7	25	83,3	0,3349	1,78	0,54	5,89	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Abdominal distension	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Gastrointestinal disorders	Abdominal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Abdominal pain lower	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1341	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1311
Gastrointestinal disorders	Abdominal pain upper	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Gastrointestinal disorders	Bowel movement irregularity	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Cheilitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Cheilitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0441	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2382
Gastrointestinal disorders	Constipation	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,3676	2,87	0,26	31,67	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0,0	71	100,0	0,0331	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Gastrointestinal disorders	Diarrhoea	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0753	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1749	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dry mouth	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3438	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Dyspepsia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders	Dysphagia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Faeces soft	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Gastrointestinal disorders	Flatulence	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Gastroesophageal reflux disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0639
Gastrointestinal disorders	Gastroesophageal reflux disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Gastrointestinal disorders	Haemorrhoids	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7815	1,48	0,09	23,62	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Hyperaesthesia teeth	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Large intestine polyp	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Mouth ulceration	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2215	3,59	0,40	32,14	Convergence criterion (GCONV=1E-8) satisfied.	0,8651
Gastrointestinal disorders	Nausea	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1477	4,58	0,48	44,12	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3539	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Stomatitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Toothache	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0295
Gastrointestinal disorders	Vomiting	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		Male	82	78,8	20	24,4	62	75,6	71	70,3	6	8,5	65	91,5	0,0077	3,24	1,30	8,08	Convergence criterion (GCONV=1E-8) satisfied.	0,1874
General disorders and administration site conditions		Female	22	21,2	5	22,7	17	77,3	30	29,7	6	20,0	24	80,0	0,7680	1,20	0,36	3,92	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	Male	82	78,8	9	11,0	73	89,0	71	70,3	1	1,4	70	98,6	0,0175	8,16	1,03	64,47	Convergence criterion (GCONV=1E-8) satisfied.	0,0752
General disorders and administration site conditions	Asthenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Catheter site haematoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chest discomfort	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administration site conditions	Chest discomfort	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1304	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
General disorders and administration site conditions	Chest pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3381	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Chills	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6306	1,79	0,16	19,71	Convergence criterion (GCONV=1E-8) satisfied.	0,8971
General disorders and administration site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8161	1,39	0,09	22,18	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Gait disturbance	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
General disorders and administration site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2518	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Oedema	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4956
General disorders and administration site conditions	Oedema peripheral	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,3727	2,84	0,26	31,37	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administration site conditions	Pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Peripheral swelling	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
General disorders and administration site conditions	Peripheral swelling	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Male	82	78,8	10	12,2	72	87,8	71	70,3	0	0,0	71	100,0	0,0024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administration site conditions	Pyrexia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	1	1,4	70	98,6	0,1289	4,55	0,53	38,92	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9526	0,92	0,06	14,71	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Hepatobiliary disorders	Hepatic steatosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3387	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Hyperbilirubin aemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Immune system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Immune system disorders	Hypersensitivity	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Male	82	78,8	36	43,9	46	56,1	71	70,3	17	23,9	54	76,1	0,0027	2,37	1,32	4,23	Convergence criterion (GCONV=1E-8) satisfied.	0,0145
Infections and infestations		Female	22	21,2	9	40,9	13	59,1	30	29,7	18	60,0	12	40,0	0,3888	0,70	0,31	1,57	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	4	5,6	67	94,4	0,1342	0,22	0,02	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,9972
Infections and infestations	Bronchitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Candida infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Conjunctivitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1887	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2694
Infections and infestations	Cystitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,6505	1,88	0,12	30,08	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Empyema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4275	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Fungal pharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Furuncle	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Gastroenteritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4386	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastrointestinal bacterial overgrowth	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Infections and infestations	Herpes zoster	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1771	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Infectious pleural effusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9098	0,89	0,13	6,34	Convergence criterion (GCONV=1E-8) satisfied.	0,7696
Infections and infestations	Influenza	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Laryngitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Laryngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4386	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	Male	82	78,8	8	9,8	74	90,2	71	70,3	8	11,3	63	88,7	0,8630	0,92	0,34	2,44	Convergence criterion (GCONV=1E-8) satisfied.	0,0413
Infections and infestations	Nasopharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	5	16,7	25	83,3	0,0676	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3469	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Oral fungal infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral herpes	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Otitis externa	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3485	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Otitis media	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Paronychia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3774	2,66	0,28	25,61	Convergence criterion (GCONV=1E-8) satisfied.	0,0850
Infections and infestations	Pharyngitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2459	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2239	3,57	0,40	31,93	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Pneumonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia pneumococcal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Prostate infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Pulpitis dental	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3575	2,77	0,29	26,61	Convergence criterion (GCONV=1E-8) satisfied.	0,2015

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Respiratory tract infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1816	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Respiratory tract infection viral	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Infections and infestations	Rhinitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Sepsis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1820	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Sinusitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Skin infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Skin infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Tinea infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2162	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Infections and infestations	Tonsillitis	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2906	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Infections and infestations	Tooth abscess	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Tracheitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3638	2,73	0,28	26,29	Convergence criterion (GCONV=1E-8) satisfied.	0,0299
Infections and infestations	Upper respiratory tract infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	4	13,3	26	86,7	0,1048	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Urinary tract infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,8988	0,86	0,08	9,44	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Vaginal infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Viral infection	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1828	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Viral infection	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Infections and infestations	Viral upper respiratory tract infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		Male	82	78,8	5	6,1	77	93,9	71	70,3	1	1,4	70	98,6	0,1286	4,55	0,53	38,96	Convergence criterion (GCONV=1E-8) satisfied.	0,2675
Injury, poisoning and procedural complications		Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9635	1,04	0,17	6,26	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Contusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Eye contusion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1828	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0747
Injury, poisoning and procedural complications	Fall	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Joint dislocation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0687
Injury, poisoning and procedural complications	Ligament sprain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Limb injury	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Injury, poisoning and procedural complications	Rib fracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Injury, poisoning and procedural complications	Vascular access site pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	30	36,6	52	63,4	71	70,3	5	7,0	66	93,0	<.0001	6,38	2,47	16,47	Convergence criterion (GCONV=1E-8) satisfied.	0,1057
Investigations		Female	22	21,2	4	18,2	18	81,8	30	29,7	4	13,3	26	86,7	0,5467	1,53	0,38	6,12	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Male	82	78,8	6	7,3	76	92,7	71	70,3	2	2,8	69	97,2	0,2036	2,71	0,55	13,42	Convergence criterion (GCONV=1E-8) satisfied.	0,9888
Investigations	Alanine aminotransferase increased	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,4086	2,65	0,24	29,23	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	4	4,9	78	95,1	71	70,3	2	2,8	69	97,2	0,5010	1,78	0,33	9,70	Convergence criterion (GCONV=1E-8) satisfied.	0,8882
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8404	1,33	0,08	21,28	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1023	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Investigations	Blood alkaline phosphatase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood bilirubin increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood bilirubin increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood cholesterol increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood creatine increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1016	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood creatine phosphokinase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	Male	82	78,8	6	7,3	76	92,7	71	70,3	1	1,4	70	98,6	0,0733	5,56	0,67	46,19	Convergence criterion (GCONV=1E-8) satisfied.	0,2726
Investigations	Blood creatinine increased	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0258	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1914	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Investigations	Blood iron decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood lactate dehydrogenase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood lactate dehydrogenase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Blood magnesium decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3001	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Investigations	Blood pressure increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0538	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Investigations	Blood thyroid stimulating hormone decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood triglycerides increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6495	1,73	0,16	19,11	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Blood uric acid increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Creatinine renal clearance decreased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9184	0,87	0,05	13,84	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Gamma-glutamyltransferase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Gastric pH decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	International normalised ratio increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	International normalised ratio increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Liver function test increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0716
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2322	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Oxygen saturation decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Transaminases increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Urine bilirubin increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	Weight decreased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3664	2,72	0,28	26,16	Convergence criterion (GCONV=1E-8) satisfied.	0,9111
Investigations	Weight increased	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2656	3,58	0,32	39,50	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	14	17,1	68	82,9	71	70,3	10	14,1	61	85,9	0,6270	1,22	0,54	2,76	Convergence criterion (GCONV=1E-8) satisfied.	0,1148
Metabolism and nutrition disorders		Female	22	21,2	6	27,3	16	72,7	30	29,7	2	6,7	28	93,3	0,0343	4,78	0,96	23,72	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Decreased appetite	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3966	2,57	0,27	24,70	Convergence criterion (GCONV=1E-8) satisfied.	0,3894
Metabolism and nutrition disorders	Decreased appetite	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Metabolism and nutrition disorders	Dehydration	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1327	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9956
Metabolism and nutrition disorders	Hypercholesterolaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4858	0,44	0,04	4,81	Convergence criterion (GCONV=1E-8) satisfied.	0,1298
Metabolism and nutrition disorders	Hyperglycaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6420	1,75	0,16	19,34	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6439	1,75	0,16	19,28	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Metabolism and nutrition disorders	Hyperuricaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypoglycaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0997	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Metabolism and nutrition disorders	Hypomagnesaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0694
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Metabolism and nutrition disorders	Hypovolaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Iron deficiency	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Metabolism and nutrition disorders	Vitamin D deficiency	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Male	82	78,8	24	29,3	58	70,7	71	70,3	9	12,7	62	87,3	0,0070	2,76	1,28	5,97	Convergence criterion (GCONV=1E-8) satisfied.	0,3572
Musculoskeletal and connective tissue disorders		Female	22	21,2	7	31,8	15	68,2	30	29,7	8	26,7	22	73,3	0,5119	1,40	0,51	3,89	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	Male	82	78,8	8	9,8	74	90,2	71	70,3	2	2,8	69	97,2	0,0763	3,70	0,78	17,43	Convergence criterion (GCONV=1E-8) satisfied.	0,8347
Musculoskeletal and connective tissue disorders	Arthralgia	Female	22	21,2	5	22,7	17	77,3	30	29,7	3	10,0	27	90,0	0,1372	2,83	0,67	11,89	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1295

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4237	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	Male	82	78,8	3	3,7	79	96,3	71	70,3	3	4,2	68	95,8	0,9666	1,04	0,20	5,25	Convergence criterion (GCONV=1E-8) satisfied.	0,8916
Musculoskeletal and connective tissue disorders	Back pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,7923	0,73	0,07	8,00	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Musculoskeletal and connective tissue disorders	Bone pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7671	1,52	0,09	24,24	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Coccydynia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9317	0,89	0,06	14,16	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Limb discomfort	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Muscle fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3485	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1830	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0907	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0967	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2260	3,55	0,40	31,77	Convergence criterion (GCONV=1E-8) satisfied.	0,1574
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Neck pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3578	2,77	0,29	26,60	Convergence criterion (GCONV=1E-8) satisfied.	0,4287
Musculoskeletal and connective tissue disorders	Pain in extremity	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,7587	0,69	0,06	7,59	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Musculoskeletal and connective tissue disorders	Periarthritis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Spinal pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Spinal pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders	Synovial cyst	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Tendonitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	4	4,9	78	95,1	71	70,3	3	4,2	68	95,8	0,7698	1,25	0,28	5,62	Convergence criterion (GCONV=1E-8) satisfied.	0,8675

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7106	1,68	0,11	26,89	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2813	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	16	19,5	66	80,5	71	70,3	15	21,1	56	78,9	0,9162	0,96	0,48	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,2196
Nervous system disorders		Female	22	21,2	10	45,5	12	54,5	30	29,7	8	26,7	22	73,3	0,1612	1,93	0,76	4,90	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Arachnoid cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Arachnoid cyst	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Cerebral arteriosclerosis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Cognitive disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Disturbance in attention	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	Male	82	78,8	3	3,7	79	96,3	71	70,3	2	2,8	69	97,2	0,7357	1,36	0,23	8,14	Convergence criterion (GCONV=1E-8) satisfied.	0,1232
Nervous system disorders	Dizziness	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0838	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dysaesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Dysaesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Encephalopathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9386	0,93	0,13	6,57	Convergence criterion (GCONV=1E-8) satisfied.	0,7026
Nervous system disorders	Headache	Female	22	21,2	3	13,6	19	86,4	30	29,7	3	10,0	27	90,0	0,6443	1,46	0,29	7,28	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1290	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
Nervous system disorders	Hypoaesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Lethargy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Loss of consciousness	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Memory impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Migraine	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Myelopathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Neuropathy peripheral	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2124	3,68	0,41	32,98	Convergence criterion (GCONV=1E-8) satisfied.	0,2922
Nervous system disorders	Neuropathy peripheral	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Neurotoxicity	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9256	0,91	0,13	6,47	Convergence criterion (GCONV=1E-8) satisfied.	0,2209
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Nervous system disorders	Parosmia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2367	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6189	1,82	0,17	20,10	Convergence criterion (GCONV=1E-8) satisfied.	0,3225

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	2	2,8	69	97,2	0,1360	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9955
Nervous system disorders	Polyneuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Seizure	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9223	0,87	0,05	13,92	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Somnolence	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9123	0,86	0,05	13,69	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Tension headache	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Transient ischaemic attack	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Upper motor neurone lesion	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2348	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Vocal cord paralysis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		Male	82	78,8	4	4,9	78	95,1	71	70,3	2	2,8	69	97,2	0,3780	2,13	0,38	11,87	Convergence criterion (GCONV=1E-8) satisfied.	0,9738
Psychiatric disorders		Female	22	21,2	3	13,6	19	86,4	30	29,7	3	10,0	27	90,0	0,5291	1,66	0,33	8,27	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0524	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Psychiatric disorders	Anxiety	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0669	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Psychiatric disorders	Depressed mood	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1205
Psychiatric disorders	Depression	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,2839	3,43	0,31	37,90	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Insomnia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Psychiatric disorders	Insomnia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Psychiatric disorders	Mental status changes	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4142	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3001	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Psychiatric disorders	Psychiatric symptom	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Psychiatric disorders	Sleep disorder	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	5	6,1	77	93,9	71	70,3	3	4,2	68	95,8	0,5637	1,52	0,36	6,37	Convergence criterion (GCONV=1E-8) satisfied.	0,9959

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7751	1,49	0,09	23,90	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Acute kidney injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3313	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9493	0,91	0,06	14,62	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Dysuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Renal and urinary disorders	Lower urinary tract symptoms	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Micturition disorder	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Renal and urinary disorders	Micturition disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4237	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Renal and urinary disorders	Pollakiuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Proteinuria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Renal and urinary disorders	Renal cyst	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Renal impairment	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Urinary tract pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6419	1,75	0,16	19,35	Convergence criterion (GCONV=1E-8) satisfied.	0,9197
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7993	1,43	0,09	22,88	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2776	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Reproductive system and breast disorders	Balanoposthitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Reproductive system and breast disorders	Breast discharge	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3570	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Breast pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Gynaecomastia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	27	32,9	55	67,1	71	70,3	13	18,3	58	81,7	0,0212	2,16	1,10	4,22	Convergence criterion (GCONV=1E-8) satisfied.	0,2003
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	4	18,2	18	81,8	30	29,7	7	23,3	23	76,7	0,6921	0,78	0,23	2,68	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,3033	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Catarrh	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	Male	82	78,8	13	15,9	69	84,1	71	70,3	7	9,9	64	90,1	0,2288	1,75	0,69	4,41	Convergence criterion (GCONV=1E-8) satisfied.	0,5935
Respiratory, thoracic and mediastinal disorders	Cough	Female	22	21,2	2	9,1	20	90,9	30	29,7	3	10,0	27	90,0	0,9501	0,94	0,16	5,66	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Dysphonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	7	8,5	75	91,5	71	70,3	3	4,2	68	95,8	0,1895	2,45	0,62	9,73	Convergence criterion (GCONV=1E-8) satisfied.	0,4702
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,8005	0,73	0,07	8,11	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3552	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1821	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Lung disorder	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Male	82	78,8	2	2,4	80	97,6	71	70,3	2	2,8	69	97,2	0,9179	0,90	0,13	6,40	Convergence criterion (GCONV=1E-8) satisfied.	0,1938

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2089	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Respiratory, thoracic and mediastinal disorders	Pleurisy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3918	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1030	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,0027	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,0938	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Productive cough	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Rales	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Rales	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1805	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	25	30,5	57	69,5	71	70,3	3	4,2	68	95,8	<.0001	8,66	2,61	28,69	Convergence criterion (GCONV=1E-8) satisfied.	0,8416
Skin and subcutaneous tissue disorders		Female	22	21,2	11	50,0	11	50,0	30	29,7	3	10,0	27	90,0	0,0004	7,21	2,00	25,96	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Actinic keratosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0844
Skin and subcutaneous tissue disorders	Alopecia	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1364	4,76	0,49	45,84	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2966	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Skin and subcutaneous tissue disorders	Dermatitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Male	82	78,8	3	3,7	79	96,3	71	70,3	0	0,0	71	100,0	0,1011	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3347	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Drug eruption	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1751	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Skin and subcutaneous tissue disorders	Dry skin	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0670	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Erythema	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Skin and subcutaneous tissue disorders	Miliaria	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Onychoclasia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Papule	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Pruritus	Male	82	78,8	9	11,0	73	89,0	71	70,3	1	1,4	70	98,6	0,0144	8,53	1,08	67,38	Convergence criterion (GCONV=1E-8) satisfied.	0,7261
Skin and subcutaneous tissue disorders	Pruritus	Female	22	21,2	3	13,6	19	86,4	30	29,7	1	3,3	29	96,7	0,1233	4,97	0,52	47,75	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1747	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Skin and subcutaneous tissue disorders	Psoriasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0,0	71	100,0	0,0325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash erythematous	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash maculo-papular	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash pruritic	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Scar pain	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Skin burning sensation	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Toxic skin eruption	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Toxic skin eruption	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Urticaria	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Vitiligo	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Surgical and medical procedures		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Surgical and medical proceders	Cancer surgery	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	3	4,2	68	95,8	0,8922	0,90	0,18	4,44	Convergence criterion (GCONV=1E-8) satisfied.	0,6801
Vascular disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	2	6,7	28	93,3	0,6293	1,61	0,23	11,48	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Hot flush	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1737	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Hypertension	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0763	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Vascular disorders	Hypotension	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Orthostatic hypotension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Vascular disorders	Orthostatic hypotension	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Phlebitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Phlebitis superficial	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2846	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Vascular disorders	Vascular stenosis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

MODEL: Unstratified analysis

STUDY: GO29527

Time to Event Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	9	14,1	55	85,9	62	61,4	5	8,1	57	91,9	0,2436	1,90	0,63	5,67	Convergence criterion (GCONV=1E-8) satisfied.	0,8632
Blood and lymphatic system disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6185	1,57	0,26	9,40	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	5	8,1	57	91,9	0,9684	1,03	0,30	3,54	Convergence criterion (GCONV=1E-8) satisfied.	0,6992
Blood and lymphatic system disorders	Anaemia	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6185	1,57	0,26	9,40	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Lymphadenopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9994	1,00	0,06	16,01	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Sarcoidosis of lymph node	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0738	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Cardiac disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Cardiac disorders	Atrial fibrillation	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Cardiac failure	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Cardiac failure chronic	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Metabolic cardiomyopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Palpitations	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2969	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3121	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Sinus bradycardia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Congenital, familial and genetic disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Congenital, familial and genetic disorders	Gilbert's syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5267	2,13	0,19	23,51	Convergence criterion (GCONV=1E-8) satisfied.	0,0443
Ear and labyrinth disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	3	7,7	36	92,3	0,0780	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Ear and labyrinth disorders	Ear discomfort	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Ear and labyrinth disorders	Ear discomfort	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3270	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Ear and labyrinth disorders	Tinnitus	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1520	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Ear and labyrinth disorders	Vertigo	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Ear and labyrinth disorders	Vestibular ataxia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	12	18,8	52	81,3	62	61,4	1	1,6	61	98,4	0,0012	13,42	1,74	103,40	Convergence criterion (GCONV=1E-8) satisfied.	0,5545

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		>= 65	40	38,5	5	12,5	35	87,5	39	38,6	1	2,6	38	97,4	0,0763	5,59	0,65	47,90	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Autoimmune thyroiditis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0927	5,21	0,61	44,68	Convergence criterion (GCONV=1E-8) satisfied.	0,0823
Endocrine disorders	Hyperthyroidism	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	< 65	64	61,5	7	10,9	57	89,1	62	61,4	0	0,0	62	100,0	0,0059	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Endocrine disorders	Hypothyroidism	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0342	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5351	2,10	0,19	23,18	Convergence criterion (GCONV=1E-8) satisfied.	0,7062
Eye disorders		>= 65	40	38,5	5	12,5	35	87,5	39	38,6	4	10,3	35	89,7	0,7375	1,25	0,34	4,67	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Blepharitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3137
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9855	0,97	0,06	15,58	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Dry eye	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Eyelid oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Ocular discomfort	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Retinal detachment	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Eye disorders	Vision blurred	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Visual impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous floaters	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Vitreous floaters	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	14	21,9	50	78,1	62	61,4	10	16,1	52	83,9	0,3318	1,49	0,66	3,36	Convergence criterion (GCONV=1E-8) satisfied.	0,1555
Gastrointestinal disorders		>= 65	40	38,5	9	22,5	31	77,5	39	38,6	2	5,1	37	94,9	0,0213	5,10	1,09	23,83	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal distension	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1441	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Gastrointestinal disorders	Abdominal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal pain lower	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9895	1,02	0,06	16,30	Convergence criterion (GCONV=1E-8) satisfied.	0,1858
Gastrointestinal disorders	Abdominal pain upper	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1520	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Bowel movement irregularity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Cheilitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Cheilitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,3118	3,04	0,32	29,34	Convergence criterion (GCONV=1E-8) satisfied.	0,2670
Gastrointestinal disorders	Constipation	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0435	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Gastrointestinal disorders	Diarrhoea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0751	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dry mouth	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3133	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Dyspepsia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Dysphagia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Faeces soft	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Flatulence	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Gastroesophageal reflux disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9698	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Gastroesophageal reflux disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9951	1,01	0,06	16,13	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Haemorrhoids	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Hyperaesthesia teeth	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Large intestine polyp	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Mouth ulceration	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	< 65	64	61,5	4	6,3	60	93,8	62	61,4	2	3,2	60	96,8	0,3936	2,06	0,38	11,25	Convergence criterion (GCONV=1E-8) satisfied.	0,1661
Gastrointestinal disorders	Nausea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0772	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Stomatitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Toothache	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5208	2,16	0,19	23,97	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Gastrointestinal disorders	Vomiting	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		< 65	64	61,5	15	23,4	49	76,6	62	61,4	6	9,7	56	90,3	0,0281	2,77	1,07	7,13	Convergence criterion (GCONV=1E-8) satisfied.	0,5565
General disorders and administration site conditions		>= 65	40	38,5	10	25,0	30	75,0	39	38,6	6	15,4	33	84,6	0,2508	1,80	0,65	4,97	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0908	5,25	0,61	44,92	Convergence criterion (GCONV=1E-8) satisfied.	0,8511
General disorders and administration site conditions	Asthenia	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	1	2,6	38	97,4	0,1894	3,90	0,44	34,90	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Catheter site haematoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Chest discomfort	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administration site conditions	Chest discomfort	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2943	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions	Chest pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Chills	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5511	2,04	0,19	22,55	Convergence criterion (GCONV=1E-8) satisfied.	0,6866
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9836	0,97	0,06	15,53	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions	Gait disturbance	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1650	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Oedema	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,3061	3,07	0,32	29,53	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions	Oedema peripheral	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Peripheral swelling	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Peripheral swelling	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0245	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	0	0,0	39	100,0	0,0124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1544	4,30	0,48	38,51	Convergence criterion (GCONV=1E-8) satisfied.	0,5326
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9698	1,06	0,07	16,89	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Hepatic steatosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Hyperbilirubin aemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0799	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9963
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0799	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9963
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections		< 65	64	61,5	26	40,6	38	59,4	62	61,4	23	37,1	39	62,9	0,3721	1,29	0,74	2,26	Convergence criterion (GCONV=1E-8) satisfied.	0,4033
Infestations and infections		>= 65	40	38,5	19	47,5	21	52,5	39	38,6	12	30,8	27	69,2	0,0666	1,95	0,94	4,04	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections	Bronchitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1742	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2818
Infestations and infections	Bronchitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	2	5,1	37	94,9	0,5299	0,47	0,04	5,20	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections	Candida infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Candida infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Conjunctivitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0428
Infections and infestations	Cystitis	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0880	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3399	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Empyema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Fungal pharyngitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Furuncle	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Gastroenteritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastrointestinal bacterial overgrowth	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3017	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Herpes zoster	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Infectious pleural effusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	< 65	64	61,5	1	1,6	63	98,4	62	61,4	3	4,8	59	95,2	0,3307	0,34	0,04	3,29	Convergence criterion (GCONV=1E-8) satisfied.	0,0498
Infections and infestations	Influenza	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1599	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Laryngitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Laryngitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	< 65	64	61,5	6	9,4	58	90,6	62	61,4	8	12,9	54	87,1	0,6936	0,81	0,28	2,33	Convergence criterion (GCONV=1E-8) satisfied.	0,4502
Infections and infestations	Nasopharyngitis	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	5	12,8	34	87,2	0,2273	0,38	0,07	1,95	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Oral fungal infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral herpes	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Otitis externa	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Otitis media	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Paronychia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,2972	3,13	0,33	30,13	Convergence criterion (GCONV=1E-8) satisfied.	0,0458
Infections and infestations	Pharyngitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1547	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia	< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1624	4,20	0,47	37,64	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Infections and infestations	Pneumonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia pneumococcal	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Prostate infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3343	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pulpitis dental	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5858	0,52	0,05	5,73	Convergence criterion (GCONV=1E-8) satisfied.	0,0925

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Respiratory tract infection	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1425	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1436	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Infections and infestations	Respiratory tract infection viral	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Rhinitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Sepsis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Sinusitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Skin infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Skin infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Tinea infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Infections and infestations	Tonsillitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3399	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tooth abscess	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tracheitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9637	1,05	0,15	7,43	Convergence criterion (GCONV=1E-8) satisfied.	0,4375
Infections and infestations	Upper respiratory tract infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	3	7,7	36	92,3	0,3053	0,32	0,03	3,13	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0483
Infections and infestations	Urinary tract infection	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1591	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Vaginal infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Viral infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Viral infection	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1667	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Viral upper respiratory tract infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		< 65	64	61,5	4	6,3	60	93,8	62	61,4	1	1,6	61	98,4	0,1558	4,29	0,48	38,35	Convergence criterion (GCONV=1E-8) satisfied.	0,2579
Injury, poisoning and procedural complications		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	3	7,7	36	92,3	0,9639	0,96	0,19	4,78	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Contusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Eye contusion	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Injury, poisoning and procedural complications	Fall	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5813	1,94	0,18	21,40	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Fracture	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3245	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Joint dislocation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0927
Injury, poisoning and procedural complications	Ligament sprain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Injury, poisoning and procedural complications	Limb injury	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3395	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Rib fracture	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Injury, poisoning and procedural complications	Vascular access site pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	23	35,9	41	64,1	62	61,4	7	11,3	55	88,7	0,0006	3,98	1,70	9,30	Convergence criterion (GCONV=1E-8) satisfied.	0,6015

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		>= 65	40	38,5	11	27,5	29	72,5	39	38,6	2	5,1	37	94,9	0,0082	5,98	1,32	26,99	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	< 65	64	61,5	5	7,8	59	92,2	62	61,4	3	4,8	59	95,2	0,4667	1,69	0,40	7,08	Convergence criterion (GCONV=1E-8) satisfied.	0,1321
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0836	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	3	4,8	59	95,2	0,9884	1,01	0,20	5,02	Convergence criterion (GCONV=1E-8) satisfied.	0,1351
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1458	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Investigations	Blood alkaline phosphatase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood bilirubin increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood bilirubin increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood cholesterol increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood cholesterol increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood creatine increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1529	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Investigations	Blood creatine phosphokinase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	< 65	64	61,5	6	9,4	58	90,6	62	61,4	0	0,0	62	100,0	0,0102	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1563
Investigations	Blood creatinine increased	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,3180	3,00	0,31	28,81	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1606	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood iron decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood lactate dehydrogenase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood magnesium decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3297	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood pressure increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0790	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Blood thyroid stimulating hormone decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood triglycerides increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Blood triglycerides increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2925
Investigations	Blood uric acid increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9504	0,92	0,06	14,68	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Creatinine renal clearance decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9685	1,06	0,07	16,91	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Gamma-glutamyltransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Gastric pH decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	International normalised ratio increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Investigations	Liver function test increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5690	0,50	0,05	5,57	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Oxygen saturation decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Transaminases increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3023	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Transaminases increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Urine bilirubin increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,0943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Investigations	Weight decreased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	< 65	64	61,5	3	4,7	61	95,3	62	61,4	1	1,6	61	98,4	0,3021	3,10	0,32	29,79	Convergence criterion (GCONV=1E-8) satisfied.	0,8189
Investigations	Weight increased	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5263	2,13	0,19	23,57	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	16	25,0	48	75,0	62	61,4	6	9,7	56	90,3	0,0183	2,94	1,15	7,52	Convergence criterion (GCONV=1E-8) satisfied.	0,0490

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		>= 65	40	38,5	4	10,0	36	90,0	39	38,6	6	15,4	33	84,6	0,4871	0,64	0,18	2,28	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1256
Metabolism and nutrition disorders	Decreased appetite	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9929	0,99	0,06	15,79	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1488	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Metabolism and nutrition disorders	Dehydration	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Metabolism and nutrition disorders	Hypercholesterolaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1542	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5341	2,10	0,19	23,22	Convergence criterion (GCONV=1E-8) satisfied.	0,1787
Metabolism and nutrition disorders	Hyperglycaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1589	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0485
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3021
Metabolism and nutrition disorders	Hyperuricaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9929	0,99	0,06	15,79	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypoglycaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1474	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1514	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypomagnesaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9925	1,01	0,06	16,21	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypovolaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Iron deficiency	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Iron deficiency	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Vitamin D deficiency	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	18	28,1	46	71,9	62	61,4	10	16,1	52	83,9	0,0826	1,96	0,90	4,25	Convergence criterion (GCONV=1E-8) satisfied.	0,8478
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	13	32,5	27	67,5	39	38,6	7	17,9	32	82,1	0,0564	2,41	0,95	6,14	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	< 65	64	61,5	7	10,9	57	89,1	62	61,4	3	4,8	59	95,2	0,1663	2,52	0,65	9,73	Convergence criterion (GCONV=1E-8) satisfied.	0,8171
Musculoskeletal and connective tissue disorders	Arthralgia	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	2	5,1	37	94,9	0,1230	3,28	0,66	16,28	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3314	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985
Musculoskeletal and connective tissue disorders	Arthritis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	< 65	64	61,5	4	6,3	60	93,8	62	61,4	3	4,8	59	95,2	0,6914	1,35	0,30	6,04	Convergence criterion (GCONV=1E-8) satisfied.	0,0912
Musculoskeletal and connective tissue disorders	Back pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,2227	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1024
Musculoskeletal and connective tissue disorders	Bone pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Coccydynia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9868	0,98	0,06	15,68	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Limb discomfort	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscle fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscle spasms	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1623	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1753	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9981	1,00	0,06	16,05	Convergence criterion (GCONV=1E-8) satisfied.	0,5376
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,2960	3,14	0,33	30,21	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Neck pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2987	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Osteoarthritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	< 65	64	61,5	4	6,3	60	93,8	62	61,4	2	3,2	60	96,8	0,3817	2,10	0,38	11,46	Convergence criterion (GCONV=1E-8) satisfied.	0,1620
Musculoskeletal and connective tissue disorders	Pain in extremity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Periarthritis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Spinal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Synovial cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Tendonitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9722	1,04	0,15	7,35	Convergence criterion (GCONV=1E-8) satisfied.	0,7918
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,5830	1,65	0,27	10,04	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		< 65	64	61,5	13	20,3	51	79,7	62	61,4	14	22,6	48	77,4	0,9206	0,96	0,45	2,05	Convergence criterion (GCONV=1E-8) satisfied.	0,4495
Nervous system disorders		>= 65	40	38,5	13	32,5	27	67,5	39	38,6	9	23,1	30	76,9	0,3537	1,49	0,64	3,49	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Arachnoid cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral arteriosclerosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebral infarction	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cognitive disorder	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Disturbance in attention	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Dizziness	< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9843	1,02	0,14	7,24	Convergence criterion (GCONV=1E-8) satisfied.	0,0897
Nervous system disorders	Dizziness	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Dysaesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Encephalopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	< 65	64	61,5	4	6,3	60	93,8	62	61,4	3	4,8	59	95,2	0,6668	1,39	0,31	6,20	Convergence criterion (GCONV=1E-8) satisfied.	0,4788
Nervous system disorders	Headache	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	2	5,1	37	94,9	0,5916	0,52	0,05	5,78	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Hypoaesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	2	5,1	37	94,9	0,1519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Lethargy	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Loss of consciousness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Memory impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Migraine	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Myelopathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3314	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Myelopathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0240	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0828
Nervous system disorders	Neuropathy peripheral	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9677	1,06	0,07	16,95	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Neurotoxicity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	2	3,1	62	96,9	62	61,4	3	4,8	59	95,2	0,6808	0,69	0,11	4,13	Convergence criterion (GCONV=1E-8) satisfied.	0,3430
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Parosmia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9855	1,03	0,06	16,40	Convergence criterion (GCONV=1E-8) satisfied.	0,1840
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1590	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Nervous system disorders	Polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Seizure	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Somnolence	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9865	0,98	0,06	15,61	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Somnolence	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9552	0,92	0,06	14,78	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Tension headache	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Transient ischaemic attack	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3126	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Upper motor neurone lesion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Vocal cord paralysis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	4	6,5	58	93,5	0,9410	1,05	0,26	4,21	Convergence criterion (GCONV=1E-8) satisfied.	0,4266
Psychiatric disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	1	2,6	38	97,4	0,2257	3,72	0,38	36,30	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Psychiatric disorders	Anxiety	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Depressed mood	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Depression	< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5355	2,10	0,19	23,16	Convergence criterion (GCONV=1E-8) satisfied.	0,1908
Psychiatric disorders	Depression	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Psychiatric disorders	Insomnia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3270	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Mental status changes	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3297	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Psychiatric disorders	Psychiatric symptom	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Sleep disorder	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	2	3,2	60	96,8	0,6108	1,59	0,26	9,49	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Renal and urinary disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	2	5,1	37	94,9	0,6368	1,54	0,26	9,24	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Acute kidney injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1462	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0952
Renal and urinary disorders	Dysuria	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Lower urinary tract symptoms	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Renal and urinary disorders	Micturition disorder	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3017	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Pollakiuria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Proteinuria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Renal cyst	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Renal impairment	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Urinary tract pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5451	2,06	0,19	22,78	Convergence criterion (GCONV=1E-8) satisfied.	0,6809
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9651	0,94	0,06	15,03	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Balanoposthitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,2935	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Breast discharge	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Breast discharge	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Breast pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Reproductive system and breast disorders	Gynaecomastia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	17	26,6	47	73,4	62	61,4	11	17,7	51	82,3	0,1304	1,81	0,83	3,94	Convergence criterion (GCONV=1E-8) satisfied.	0,8933

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	14	35,0	26	65,0	39	38,6	9	23,1	30	76,9	0,1900	1,74	0,75	4,04	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Catarrh	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3442	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	< 65	64	61,5	7	10,9	57	89,1	62	61,4	6	9,7	56	90,3	0,6372	1,31	0,43	3,97	Convergence criterion (GCONV=1E-8) satisfied.	0,5168
Respiratory, thoracic and mediastinal disorders	Cough	>= 65	40	38,5	8	20,0	32	80,0	39	38,6	4	10,3	35	89,7	0,2384	2,03	0,61	6,74	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dysphonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	4	6,3	60	93,8	62	61,4	2	3,2	60	96,8	0,2572	2,68	0,46	15,55	Convergence criterion (GCONV=1E-8) satisfied.	0,7225
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	3	7,7	36	92,3	0,6588	1,40	0,31	6,25	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Haemoptysis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3121	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Haemoptysis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Laryngospasm	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Lung disorder	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Nasal congestion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	< 65	64	61,5	3	4,7	61	95,3	62	61,4	2	3,2	60	96,8	0,6158	1,57	0,26	9,43	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pleurisy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,0343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1546	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Productive cough	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1439	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Productive cough	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1374	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Rales	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1554	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0805	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	16	25,0	48	75,0	62	61,4	2	3,2	60	96,8	0,0003	9,45	2,17	41,17	Convergence criterion (GCONV=1E-8) satisfied.	0,6627
Skin and subcutaneous tissue disorders		>= 65	40	38,5	20	50,0	20	50,0	39	38,6	4	10,3	35	89,7	<.0001	6,45	2,20	18,91	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Actinic keratosis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9877	1,02	0,06	16,36	Convergence criterion (GCONV=1E-8) satisfied.	0,7044
Skin and subcutaneous tissue disorders	Alopecia	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	1	2,6	38	97,4	0,5411	2,08	0,19	22,97	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Dermatitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3372	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3213	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Dermatitis acneiform	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1427	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Drug eruption	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dry skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2904	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Skin and subcutaneous tissue disorders	Erythema	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Miliaria	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3245	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Onychoclasia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Papule	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	< 65	64	61,5	6	9,4	58	90,6	62	61,4	1	1,6	61	98,4	0,0437	6,60	0,79	54,81	Convergence criterion (GCONV=1E-8) satisfied.	0,9815
Skin and subcutaneous tissue disorders	Pruritus	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	1	2,6	38	97,4	0,0506	6,30	0,76	52,34	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Skin and subcutaneous tissue disorders	Psoriasis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3101	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	5	7,8	59	92,2	62	61,4	0	0,0	62	100,0	0,0225	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0,0	39	100,0	0,0863	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash erythematous	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash maculo-papular	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2947	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders	Rash pruritic	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Scar pain	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3109	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Skin burning sensation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Skin exfoliation	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Skin exfoliation	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Toxic skin eruption	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Urticaria	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Vitiligo	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Surgical and medical procedures		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Surgical and medical procedures	Cancer surgery	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9698	1,04	0,15	7,38	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		>= 65	40	38,5	3	7,5	37	92,5	39	38,6	3	7,7	36	92,3	0,9558	1,05	0,21	5,19	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hot flush	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders	Hypertension	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1377	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypotension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypotension	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Orthostatic hypotension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Phlebitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3112	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Phlebitis superficial	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Vascular stenosis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3110	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 17:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0613
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	7	10,3	61	89,7	0,8318	1,12	0,39	3,20	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1166
Blood and lymphatic system disorders	Anaemia	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	7	10,3	61	89,7	0,6865	0,79	0,25	2,49	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1208	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Lymphadenopathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2834
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1995	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	0	0,0	68	100,0	0,0304	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Cardiac disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure chronic	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Cardiac failure chronic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Metabolic cardiomyopathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Palpitations	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3711	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Sinus bradycardia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Sinus bradycardia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Congenital, familial and genetic disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Congenital, familial and genetic disorders	Gilbert's syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8258

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9873	1,02	0,06	16,36	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	3	30,0	7	70,0	0,3203	0,34	0,03	3,23	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Ear discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Tinnitus	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1695	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders	Vertigo	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vestibular ataxia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Asia Pacific and Austral ia	29	27,9	5	17,2	24	82,8	23	22,8	1	4,3	22	95,7	0,1253	4,63	0,54	39,81	Convergence criterion (GCONV=1E-8) satisfied.	0,6384
Endocrine disorders		Europe and Middle East	65	62,5	10	15,4	55	84,6	68	67,3	1	1,5	67	98,5	0,0029	11,72	1,50	91,68	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders	Autoimmune thyroiditis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Autoimmune thyroiditis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6590	1,71	0,15	19,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9283
Endocrine disorders	Hyperthyroidism	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2750	3,29	0,34	31,62	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1853	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Hypothyroidism	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	0	0,0	68	100,0	0,0043	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	2	8,7	21	91,3	0,4951	1,79	0,33	9,78	Convergence criterion (GCONV=1E-8) satisfied.	0,9180
Eye disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	3	4,4	65	95,6	0,9091	1,10	0,22	5,44	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2664	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Blepharitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Blepharitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1723
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1620	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Dry eye	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Eyelid oedema	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Eye disorders	Eyelid oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Ocular discomfort	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Retinal detachment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vision blurred	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Vision blurred	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Visual impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous floaters	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	8	27,6	21	72,4	23	22,8	2	8,7	21	91,3	0,0988	3,42	0,72	16,13	Convergence criterion (GCONV=1E-8) satisfied.	0,5829
Gastrointestinal disorders		Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	8	11,8	60	88,2	0,3340	1,56	0,63	3,89	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	4	40,0	6	60,0	10	9,9	2	20,0	8	80,0	0,2365	2,72	0,49	15,23	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal distension	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal hernia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1319	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain lower	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2615	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3924

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain upper	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	0,9703	1,05	0,07	16,87	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Bowel movement irregularity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Cheilitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,7151
Gastrointestinal disorders	Constipation	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1242	4,79	0,53	43,27	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Diarrhoea	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	0	0,0	68	100,0	0,0352	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dry mouth	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dyspepsia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dysphagia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Faeces soft	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Flatulence	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2516
Gastrointestinal disorders	Gastrooesophageal reflux disease	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastrooesophageal reflux disease	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2161

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Haemorrhoids	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Hyperaesthesia teeth	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Large intestine polyp	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3384	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Mouth ulceration	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8155
Gastrointestinal disorders	Nausea	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2829	3,23	0,34	31,05	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	North America	10	9,6	3	30,0	7	70,0	10	9,9	1	10,0	9	90,0	0,1919	4,08	0,42	39,81	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3545	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Stomatitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Toothache	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5749
Gastrointestinal disorders	Vomiting	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9477	1,10	0,07	17,58	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	7	24,1	22	75,9	23	22,8	1	4,3	22	95,7	0,0455	6,49	0,79	53,18	Convergence criterion (GCONV=1E-8) satisfied.	0,3687
General disorders and administration site conditions		Europe and Middle East	65	62,5	16	24,6	49	75,4	68	67,3	9	13,2	59	86,8	0,0767	2,06	0,91	4,67	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions		North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,9000	1,13	0,16	8,07	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Asthenia	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	2	2,9	66	97,1	0,0224	4,99	1,08	23,12	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site haematoma	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Catheter site haematoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1714	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Chest pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chills	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5187
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	2	2,9	66	97,1	0,9700	1,04	0,15	7,37	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Gait disturbance	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3449	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1709	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4009
General disorders and administration site conditions	Oedema peripheral	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1294	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Oedema peripheral	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	1,0000	1,00	0,06	15,99	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Peripheral swelling	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Peripheral swelling	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	0	0,0	23	100,0	0,0222	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0194	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1049	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5064
Hepatobiliary disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,4957	2,25	0,20	24,87	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic steatosis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2794
Hepatobiliary disorders	Hepatic steatosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hyperbilirubin aemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivitiy	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivitiy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivitiy	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Asia Pacific and Australia	29	27,9	17	58,6	12	41,4	23	22,8	7	30,4	16	69,6	0,0348	2,50	1,04	6,05	Convergence criterion (GCONV=1E-8) satisfied.	0,1863
Infections and infestations		Europe and Middle East	65	62,5	26	40,0	39	60,0	68	67,3	24	35,3	44	64,7	0,2355	1,40	0,80	2,44	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		North America	10	9,6	2	20,0	8	80,0	10	9,9	4	40,0	6	60,0	0,4385	0,51	0,09	2,85	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0990

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Bronchitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	4	5,9	64	94,1	0,0549	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Candida infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Conjunctivitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8881	0,82	0,05	13,12	Convergence criterion (GCONV=1E-8) satisfied.	0,4344
Infections and infestations	Cystitis	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1237	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Empyema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3346	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Fungal pharyngitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Furuncle	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastroenteritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Gastrointestinal bacterial overgrowth	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Herpes zoster	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Infectious pleural effusion	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1339	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4351
Infections and infestations	Influenza	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5823	1,64	0,27	9,84	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Laryngitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	3	13,0	20	87,0	0,8248	1,18	0,26	5,30	Convergence criterion (GCONV=1E-8) satisfied.	0,5425
Infections and infestations	Nasopharyngitis	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	10	14,7	58	85,3	0,1374	0,43	0,13	1,36	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Oral fungal infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Oral herpes	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis externa	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Otitis media	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Paronychia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8384	0,82	0,11	5,79	Convergence criterion (GCONV=1E-8) satisfied.	0,9890
Infections and infestations	Pharyngitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9717	1,05	0,07	16,81	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1104	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3726

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Pneumonia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9476	1,10	0,07	17,56	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Prostate infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Pulpitis dental	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Respiratory tract infection	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5614	1,69	0,28	10,12	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Respiratory tract infection viral	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Rhinitis	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1455	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sepsis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sinusitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Skin infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tinea infection	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth abscess	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3304	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tooth infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tracheitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	3	13,0	20	87,0	0,5130	0,55	0,09	3,32	Convergence criterion (GCONV=1E-8) satisfied.	0,1354

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Upper respiratory tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Urinary tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6420	0,57	0,05	6,29	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Vaginal infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Viral infection	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1452	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Viral upper respiratory tract infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		Asia Pacific and Austral ia	29	27,9	2	6,9	27	93,1	23	22,8	3	13,0	20	87,0	0,5176	0,56	0,09	3,34	Convergence criterion (GCONV=1E-8) satisfied.	0,0947
Injury, poisoning and procedural complications		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0772	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4523	2,44	0,22	26,91	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	Asia Pacific and Austral ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Contusion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Eye contusion	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Eye contusion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1199
Injury, poisoning and procedural complications	Fall	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Fracture	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Fracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Joint dislocation	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2864	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2180
Injury, poisoning and procedural complications	Ligament sprain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Ligament sprain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Limb injury	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Rib fracture	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Rib fracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Vascular access site pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Austral- ia	29	27,9	9	31,0	20	69,0	23	22,8	4	17,4	19	82,6	0,2390	2,00	0,62	6,50	Convergence criterion (GCONV=1E-8) satisfied.	0,1764
Investigations		Europe and Middle East	65	62,5	21	32,3	44	67,7	68	67,3	5	7,4	63	92,6	0,0001	5,45	2,05	14,50	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8736	0,85	0,12	6,06	Convergence criterion (GCONV=1E-8) satisfied.	0,2896
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	1	1,5	67	98,5	0,0865	5,34	0,62	45,69	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9065	0,85	0,05	13,56	Convergence criterion (GCONV=1E-8) satisfied.	0,5306
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,6006	1,61	0,27	9,62	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3634	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood alkaline phosphatase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1430	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Investigations	Blood bilirubin increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3634	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood bilirubin increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood bilirubin increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood cholesterol increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood creatine phosphokinase increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1961	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine phosphokinase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4867
Investigations	Blood creatinine increased	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1299	4,66	0,52	41,68	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0559	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood iron decreased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1526	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood lactate dehydrogenase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood lactate dehydrogenase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood magnesium decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood pressure increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood thyroid stimulating hormone decreased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood thyroid stimulating hormone decreased	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0621	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood triglycerides increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood uric acid increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5356	2,10	0,19	23,15	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood uric acid increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Creatinine renal clearance decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8897	0,82	0,05	13,14	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gastric pH decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Gastric pH decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	International normalised ratio increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,1824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Liver function test increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8896	0,82	0,05	13,15	Convergence criterion (GCONV=1E-8) satisfied.	0,6377
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Oxygen saturation decreased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Transaminases increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Urine bilirubin increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Urine bilirubin increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight decreased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,0626	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8459	0,82	0,12	5,85	Convergence criterion (GCONV=1E-8) satisfied.	0,1841
Investigations	Weight increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1225	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	2	8,7	21	91,3	0,2467	2,50	0,50	12,43	Convergence criterion (GCONV=1E-8) satisfied.	0,8231

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	12	18,5	53	81,5	68	67,3	9	13,2	59	86,8	0,3889	1,46	0,61	3,46	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,5176	2,17	0,20	23,92	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8110
Metabolism and nutrition disorders	Decreased appetite	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,3024	3,10	0,32	29,76	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Dehydration	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1208	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypercholesterolaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1746	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholesterolaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2615	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3607
Metabolism and nutrition disorders	Hyperglycaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5206	2,15	0,20	23,77	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1431	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6425

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9604	1,07	0,07	17,16	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6858	1,63	0,15	18,02	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperuricaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypoglycaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1882	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1438	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypomagnesaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2488

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypovolaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3428	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Iron deficiency	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Metabolism and nutrition disorders	Vitamin D deficiency	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3361	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	9	31,0	20	69,0	23	22,8	5	21,7	18	78,3	0,3240	1,72	0,58	5,16	Convergence criterion (GCONV=1E-8) satisfied.	0,0880
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	18	27,7	47	72,3	68	67,3	12	17,6	56	82,4	0,1260	1,76	0,85	3,67	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0185	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9027	0,84	0,05	13,45	Convergence criterion (GCONV=1E-8) satisfied.	0,2095
Musculoskeletal and connective tissue disorders	Arthralgia	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	4	5,9	64	94,1	0,1043	2,56	0,79	8,34	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0494	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2814
Musculoskeletal and connective tissue disorders	Arthritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8840	0,81	0,05	13,01	Convergence criterion (GCONV=1E-8) satisfied.	0,3627
Musculoskeletal and connective tissue disorders	Back pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	4	5,9	64	94,1	0,5717	0,61	0,11	3,40	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2799

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Bone pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3306	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Coccydynia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9632	1,07	0,07	17,08	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Limb discomfort	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle fatigue	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle spasms	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,2010	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1209	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2898	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6838
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	2	2,9	66	97,1	0,5929	1,62	0,27	9,71	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Neck pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3364	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Osteoarthritis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	2	8,7	21	91,3	0,8557	0,83	0,12	5,92	Convergence criterion (GCONV=1E-8) satisfied.	0,4904
Musculoskeletal and connective tissue disorders	Pain in extremity	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9787	1,04	0,06	16,60	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2963	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Periarthritis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Spinal pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Spinal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Synovial cyst	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Tendonitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	2	8,7	21	91,3	0,4603	0,42	0,04	4,59	Convergence criterion (GCONV=1E-8) satisfied.	0,5367
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5361	2,10	0,19	23,13	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4429	2,48	0,22	27,41	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2664	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Asia Pacific and Austral ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders		Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	2	8,7	21	91,3	0,4993	1,78	0,33	9,73	Convergence criterion (GCONV=1E-8) satisfied.	0,1047
Nervous system disorders		Europe and Middle East	65	62,5	15	23,1	50	76,9	68	67,3	18	26,5	50	73,5	0,6956	0,87	0,44	1,73	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	7	70,0	3	30,0	10	9,9	3	30,0	7	70,0	0,0360	3,94	1,00	15,60	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Arachnoid cyst	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral arteriosclerosis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cognitive disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cognitive disorder	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Disturbance in attention	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Dizziness	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9201	0,87	0,05	13,89	Convergence criterion (GCONV=1E-8) satisfied.	0,6538
Nervous system disorders	Dizziness	Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	1	1,5	67	98,5	0,1481	4,39	0,49	39,28	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Dysaesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Encephalopathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Headache	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9990
Nervous system disorders	Headache	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	3	4,4	65	95,6	0,8836	1,13	0,23	5,59	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,8985	1,14	0,16	8,09	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Hypoaesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1670	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Lethargy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Loss of consciousness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Memory impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Migraine	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Myelopathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Myelopathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3576	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,7676
Nervous system disorders	Neuropathy peripheral	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	North America	10	9,6	4	40,0	6	60,0	10	9,9	1	10,0	9	90,0	0,0950	5,36	0,59	48,50	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Neurotoxicity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5726
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	3	4,4	65	95,6	0,7494	0,75	0,12	4,49	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Parosmia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4472
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9363	1,12	0,07	17,90	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Polyneuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	2	2,9	66	97,1	0,1795	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Seizure	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Somnolence	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Somnolence	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9702	1,05	0,07	16,86	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2820
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Tension headache	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Transient ischaemic attack	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Transient ischaemic attack	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Upper motor neurone lesion	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3128	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Vocal cord paralysis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5490
Psychiatric disorders		Europe and Middle East	65	62,5	4	6,2	61	93,8	68	67,3	4	5,9	64	94,1	0,8598	1,13	0,28	4,54	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4451	2,48	0,22	27,52	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Anxiety	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1396	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Depressed mood	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders	Depressed mood	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4199
Psychiatric disorders	Depression	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6428	0,57	0,05	6,30	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Insomnia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Mental status changes	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Mental status changes	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Psychiatric symptom	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Sleep disorder	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1496

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	4	5,9	64	94,1	0,7923	0,82	0,18	3,66	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0,0	10	100,0	0,1343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Acute kidney injury	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Dysuria	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9259	1,14	0,07	18,26	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Lower urinary tract symptoms	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Micturition disorder	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3309	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Renal and urinary disorders	Pollakiuria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Proteinuria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal cyst	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Renal impairment	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3361	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Urinary tract pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0288
Reproductive system and breast disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0755	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Reproductive system and breast disorders	Balanoposthitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2689	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Balanoposthitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast discharge	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3127	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Gynaecomastia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	12	41,4	17	58,6	23	22,8	2	8,7	21	91,3	0,0096	5,77	1,29	25,86	Convergence criterion (GCONV=1E-8) satisfied.	0,0680
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	16	24,6	49	75,4	68	67,3	13	19,1	55	80,9	0,2411	1,57	0,73	3,35	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	3	30,0	7	70,0	10	9,9	5	50,0	5	50,0	0,4497	0,58	0,14	2,43	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Catarrh	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	Asia Pacific and Austral- ia	29	27,9	4	13,8	25	86,2	23	22,8	1	4,3	22	95,7	0,2562	3,31	0,37	29,62	Convergence criterion (GCONV=1E-8) satisfied.	0,7456
Respiratory, thoracic and mediastinal disorders	Cough	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	7	10,3	61	89,7	0,4120	1,52	0,56	4,15	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	North America	10	9,6	2	20,0	8	80,0	10	9,9	2	20,0	8	80,0	0,9444	1,07	0,15	7,65	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dysphonia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Dysphonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Austral ia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9116	0,85	0,05	13,67	Convergence criterion (GCONV=1E-8) satisfied.	0,0612
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	2	2,9	66	97,1	0,0346	4,93	0,98	24,83	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	2	20,0	8	80,0	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Haemoptysis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3124	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Austral ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Lung disorder	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3082	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Nasal congestion	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Asia Pacific and Austral- ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3384	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6073
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	2	2,9	66	97,1	0,9343	1,09	0,15	7,71	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleurisy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,1117	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,0253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0,0	23	100,0	0,0994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Productive cough	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rales	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Rales	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Asia Pacific and Austral- ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3545	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Asia Pacific and Austral- ia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1990	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Asia Pacific and Austral- ia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3428	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	12	41,4	17	58,6	23	22,8	2	8,7	21	91,3	0,0060	6,28	1,40	28,12	Convergence criterion (GCONV=1E-8) satisfied.	0,5603
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	19	29,2	46	70,8	68	67,3	2	2,9	66	97,1	<.0001	11,86	2,76	50,95	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	5	50,0	5	50,0	10	9,9	2	20,0	8	80,0	0,0793	3,98	0,76	20,94	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Actinic keratosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9287
Skin and subcutaneous tissue disorders	Alopecia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9702	1,05	0,07	16,86	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	North America	10	9,6	2	20,0	8	80,0	10	9,9	1	10,0	9	90,0	0,4734	2,35	0,21	25,97	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3449	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1944	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Dermatitis acneiform	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2813	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Drug eruption	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Dry skin	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0656	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Erythema	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1435	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Miliaria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Onychoclasia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Papule	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	1	4,3	22	95,7	0,0782	5,44	0,65	45,18	Convergence criterion (GCONV=1E-8) satisfied.	0,2274

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Pruritus	Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0158	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	North America	10	9,6	1	10,0	9	90,0	10	9,9	1	10,0	9	90,0	0,8996	1,20	0,07	19,14	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3511	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1997	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0,0	68	100,0	0,0769	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	3	30,0	7	70,0	10	9,9	0	0,0	10	100,0	0,0494	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Rash erythematous	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash maculo-papular	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash pruritic	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Scar pain	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin burning sensation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3040	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin exfoliation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2902	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Toxic skin eruption	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3527	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Urticaria	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Vitiligo	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Surgical and medical procedures		Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures	Cancer surgery	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Asia Pacific and Austral- ia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1844	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1455
Vascular disorders		Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	4	5,9	64	94,1	0,7917	0,82	0,18	3,65	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hot flush	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3458	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1844	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1385	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypotension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypotension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Orthostatic hypotension	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis superficial	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Vascular disorders	Phlebitis superficial	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Vascular stenosis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

MODEL: Unstratified analysis

STUDY: GO29527

Time to Event Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	4	12,9	27	87,1	33	32,7	3	9,1	30	90,9	0,5656	1,55	0,35	6,91	Convergence criterion (GCONV=1E-8) satisfied.	0,9633
Blood and lymphatic system disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	1	6,7	14	93,3	0,4482	2,28	0,25	20,42	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	3	5,7	50	94,3	0,4909	1,68	0,38	7,53	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	3	9,1	30	90,9	0,8656	1,15	0,23	5,69	Convergence criterion (GCONV=1E-8) satisfied.	0,9938
Blood and lymphatic system disorders	Anaemia	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9439	1,09	0,10	12,03	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Anaemia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	3	5,7	50	94,3	0,7865	1,25	0,25	6,19	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Lymphadenopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Lymphadenopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9361	1,12	0,07	17,93	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Cardiac failure chronic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Cardiac failure chronic	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders	Metabolic cardiomyopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Metabolic cardiomyopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Palpitations	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Palpitations	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Sinus bradycardia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Sinus bradycardia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Congenital, familial and genetic disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Congenital, familial and genetic disorders	Gilbert's syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	Gilbert's syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1707	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0957
Ear and labyrinth disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4352	2,52	0,23	27,77	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders	Ear discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Ear discomfort	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Tinnitus	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Tinnitus	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Ear and labyrinth disorders	Vertigo	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vertigo	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Ear and labyrinth disorders	Vestibular ataxia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	Vestibular ataxia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	8	25,8	23	74,2	33	32,7	2	6,1	31	93,9	0,0201	5,20	1,10	24,50	Convergence criterion (GCONV=1E-8) satisfied.	0,3192
Endocrine disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	0	0,0	15	100,0	0,1167	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Autoimmune thyroiditis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Autoimmune thyroiditis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidis m	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9002	1,13	0,16	8,06	Convergence criterion (GCONV=1E-8) satisfied.	0,2164

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders	Hyperthyroidism	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hyperthyroidism	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	IIA	31	29,8	5	16,1	26	83,9	33	32,7	0	0,0	33	100,0	0,0130	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Hypothyroidism	IIB	27	26,0	4	14,8	23	85,2	15	14,9	0	0,0	15	100,0	0,1167	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Hypothyroidism	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		IIA	31	29,8	5	16,1	26	83,9	33	32,7	2	6,1	31	93,9	0,1802	2,92	0,57	15,04	Convergence criterion (GCONV=1E-8) satisfied.	0,2549
Eye disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	3	5,7	50	94,3	0,4671	0,44	0,05	4,25	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Blepharitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Blepharitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9642	1,07	0,07	17,04	Convergence criterion (GCONV=1E-8) satisfied.	0,6082
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Dry eye	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Dry eye	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Dry eye	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Eyelid oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Eyelid oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Ocular discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Ocular discomfort	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Retinal detachment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Retinal detachment	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Retinal detachment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1228	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vision blurred	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vision blurred	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Visual impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Visual impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous floaters	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous floaters	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous floaters	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	7	22,6	24	77,4	33	32,7	4	12,1	29	87,9	0,2667	1,98	0,58	6,77	Convergence criterion (GCONV=1E-8) satisfied.	0,0707
Gastrointestinal disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	4	26,7	11	73,3	0,3714	0,54	0,13	2,15	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	12	26,1	34	73,9	53	52,5	4	7,5	49	92,5	0,0070	4,22	1,35	13,14	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal distension	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal distension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal distension	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3770	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4450	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Abdominal pain lower	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal pain lower	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain lower	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3271
Gastrointestinal disorders	Abdominal pain upper	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal pain upper	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9065	1,18	0,07	18,88	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Bowel movement irregularity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Bowel movement irregularity	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Cheilitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Cheilitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Cheilitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9642	1,07	0,07	17,04	Convergence criterion (GCONV=1E-8) satisfied.	0,2034
Gastrointestinal disorders	Constipation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Constipation	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0078	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Diarrhoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Diarrhoea	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1865	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Diarrhoea	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dry mouth	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dry mouth	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dyspepsia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dyspepsia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Dysphagia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Dysphagia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1797	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Dysphagia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Faeces soft	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Faeces soft	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Flatulence	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Flatulence	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Gastroesophageal reflux disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2390
Gastrointestinal disorders	Gastroesophageal reflux disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Gastroesophageal reflux disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Haemorrhoids	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Haemorrhoids	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8872	1,22	0,08	19,54	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Hyperaesthesia teeth	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Hyperaesthesia teeth	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Gastrointestinal disorders	Large intestine polyp	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Large intestine polyp	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Large intestine polyp	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Mouth ulceration	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Mouth ulceration	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9173	1,16	0,07	18,52	Convergence criterion (GCONV=1E-8) satisfied.	0,0720
Gastrointestinal disorders	Nausea	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6452	0,53	0,03	8,43	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Nausea	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0129	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Stomatitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Stomatitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Stomatitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Toothache	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Toothache	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0734
Gastrointestinal disorders	Vomiting	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1814	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Vomiting	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
General disorders and administration site conditions		IIA	31	29,8	9	29,0	22	71,0	33	32,7	5	15,2	28	84,8	0,1409	2,23	0,75	6,67	Convergence criterion (GCONV=1E-8) satisfied.	0,9788
General disorders and administration site conditions		IIB	27	26,0	5	18,5	22	81,5	15	14,9	1	6,7	14	93,3	0,3038	2,93	0,34	25,08	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIIA	46	44,2	11	23,9	35	76,1	53	52,5	6	11,3	47	88,7	0,0704	2,43	0,90	6,59	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	2	6,1	31	93,9	0,5681	1,68	0,28	10,09	Convergence criterion (GCONV=1E-8) satisfied.	0,1985
General disorders and administration site conditions	Asthenia	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Asthenia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0496	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Catheter site haematoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Catheter site haematoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Catheter site haematoma	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest discomfort	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest discomfort	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Chest pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chest pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chest pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2021	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Chills	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Chills	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1717	0,00	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0,0375
General disorders and administration site conditions	Fatigue	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1167	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Gait disturbance	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Gait disturbance	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3785	0,00	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2072	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Oedema peripheral	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0550
General disorders and administration site conditions	Oedema peripheral	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Oedema peripheral	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1074	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Peripheral swelling	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Peripheral swelling	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Peripheral swelling	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIA	31	29,8	4	12,9	27	87,1	33	32,7	0	0,0	33	100,0	0,0343	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	0	0,0	53	100,0	0,0064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0588
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0096	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2390
Hepatobiliary disorders	Hepatic steatosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic steatosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hyperbilirubin aemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hyperbilirubin aemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1412	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders																				
Infections and infestations		IIA	31	29,8	17	54,8	14	45,2	33	32,7	12	36,4	21	63,6	0,0819	1,91	0,91	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,3665
Infections and infestations		IIB	27	26,0	9	33,3	18	66,7	15	14,9	7	46,7	8	53,3	0,6674	0,80	0,30	2,18	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	19	41,3	27	58,7	53	52,5	16	30,2	37	69,8	0,1075	1,72	0,88	3,35	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Bronchitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4940
Infections and infestations	Bronchitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6543	0,54	0,03	8,60	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Bronchitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2036	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Candida infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Candida infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0495	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Conjunctivitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Conjunctivitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Conjunctivitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5610
Infections and infestations	Cystitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cystitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8633	1,28	0,08	20,46	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Empyema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Empyema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Fungal pharyngitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Fungal pharyngitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Furuncle	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Furuncle	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Gastroenteritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Gastroenteritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastroenteritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Gastrointestinal bacterial overgrowth	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Gastrointestinal bacterial overgrowth	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3810	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Herpes zoster	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Herpes zoster	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Infectious pleural effusion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Infectious pleural effusion	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2774	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Infectious pleural effusion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,8923	1,14	0,16	8,14	Convergence criterion (GCONV=1E-8) satisfied.	0,3413
Infections and infestations	Influenza	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Influenza	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3537	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Laryngitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Laryngitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Laryngitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3849	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	6	18,2	27	81,8	0,0705	0,18	0,02	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,1172
Infections and infestations	Nasopharyngitis	IIB	27	26,0	2	7,4	25	92,6	15	14,9	3	20,0	12	80,0	0,2497	0,36	0,06	2,19	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Nasopharyngitis	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	4	7,5	49	92,5	0,4315	1,69	0,45	6,28	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Oral fungal infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Oral fungal infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral fungal infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Oral herpes	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Oral herpes	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis externa	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis externa	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Otitis media	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Otitis media	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Otitis media	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2519	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Paronychia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Paronychia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	2	6,1	31	93,9	0,6311	0,56	0,05	6,18	Convergence criterion (GCONV=1E-8) satisfied.	0,5685
Infections and infestations	Pharyngitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pharyngitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9140	1,16	0,07	18,62	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Pneumonia	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0656	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3468
Infections and infestations	Pneumonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8691	1,26	0,08	20,23	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2817	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Prostate infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Prostate infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pulpitis dental	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pulpitis dental	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pulpitis dental	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1240	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1141
Infections and infestations	Respiratory tract infection	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6815	0,56	0,04	9,02	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Respiratory tract infection viral	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Respiratory tract infection viral	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1086	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Rhinitis	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1401	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Rhinitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Rhinitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sepsis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sinusitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sinusitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Skin infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Skin infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Skin infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tinea infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tinea infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tooth abscess	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tooth abscess	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth abscess	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tooth infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tooth infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tracheitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tracheitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Upper respiratory tract infection	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9074	1,12	0,16	7,98	Convergence criterion (GCONV=1E-8) satisfied.	0,7956
Infections and infestations	Upper respiratory tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Upper respiratory tract infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	3	5,7	50	94,3	0,4413	0,42	0,04	4,06	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1101
Infections and infestations	Urinary tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1814	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Urinary tract infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3827	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Vaginal infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Vaginal infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Viral infection	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Viral infection	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral infection	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Viral upper respiratory tract infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Viral upper respiratory tract infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications		IIA	31	29,8	3	9,7	28	90,3	33	32,7	2	6,1	31	93,9	0,5795	1,65	0,28	9,88	Convergence criterion (GCONV=1E-8) satisfied.	0,1272
Injury, poisoning and procedural complications		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Injury, poisoning and procedural complications		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	1	1,9	52	98,1	0,0957	5,29	0,59	47,34	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Contusion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Contusion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Eye contusion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Eye contusion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Eye contusion	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Fall	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fall	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4206	2,59	0,23	28,59	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Fracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Fracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Injury, poisoning and procedural complications	Fracture	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Joint dislocation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Joint dislocation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Ligament sprain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9419	1,11	0,07	17,73	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Ligament sprain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Injury, poisoning and procedural complications	Ligament sprain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Limb injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Limb injury	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Rib fracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Rib fracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1904	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Injury, poisoning and procedural complications	Rib fracture	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Injury, poisoning and procedural complications	Vascular access site pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	Vascular access site pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	7	22,6	24	77,4	33	32,7	7	21,2	26	78,8	0,8530	1,10	0,39	3,15	Convergence criterion (GCONV=1E-8) satisfied.	0,0019
Investigations		IIB	27	26,0	7	25,9	20	74,1	15	14,9	0	0,0	15	100,0	0,0202	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	20	43,5	26	56,5	53	52,5	2	3,8	51	96,2	<.0001	15,26	3,56	65,43	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Alanine aminotransferase increased	IIA	31	29,8	3	9,7	28	90,3	33	32,7	3	9,1	30	90,9	0,9177	1,09	0,22	5,39	Convergence criterion (GCONV=1E-8) satisfied.	0,0857
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0131	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	2	6,5	29	93,5	33	32,7	3	9,1	30	90,9	0,7240	0,73	0,12	4,34	Convergence criterion (GCONV=1E-8) satisfied.	0,1263
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood alkaline phosphatase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood alkaline phosphatase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1090	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood bilirubin increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood bilirubin increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood bilirubin increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood cholesterol increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood cholesterol increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Blood creatine phosphokinase increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood creatine phosphokinase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatine phosphokinase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1202	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,4743	2,34	0,21	25,82	Convergence criterion (GCONV=1E-8) satisfied.	0,2478
Investigations	Blood creatinine increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood creatinine increased	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	0	0,0	53	100,0	0,0052	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood iron decreased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood iron decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Investigations	Blood lactate dehydrogenase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood lactate dehydrogenase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood lactate dehydrogenase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood magnesium decreased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood magnesium decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood pressure increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood pressure increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3833	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood thyroid stimulating hormone decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood thyroid stimulating hormone decreased	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2730	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood thyroid stimulating hormone decreased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Blood triglycerides increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood triglycerides increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Blood uric acid increased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9731	1,05	0,07	16,78	Convergence criterion (GCONV=1E-8) satisfied.	0,5685
Investigations	Blood uric acid increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Investigations	Blood uric acid increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2817	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Creatinine renal clearance decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Creatinine renal clearance decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2294
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gastric pH decreased	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2827	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gastric pH decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Investigations	Gastric pH decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	International normalised ratio increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	International normalised ratio increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Liver function test increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Liver function test increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5751
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Investigations	Neutrophil count decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9065	1,18	0,07	18,88	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Oxygen saturation decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Oxygen saturation decreased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Transaminases increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Transaminases increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2620	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Urine bilirubin increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Urine bilirubin increased	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Urine bilirubin increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight decreased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,0558	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1752	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0121
Investigations	Weight increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0093	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	4	12,9	27	87,1	33	32,7	5	15,2	28	84,8	0,8434	0,88	0,24	3,26	Convergence criterion (GCONV=1E-8) satisfied.	0,5165
Metabolism and nutrition disorders		IIB	27	26,0	7	25,9	20	74,1	15	14,9	2	13,3	13	86,7	0,3668	2,03	0,42	9,79	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders		IIIA	46	44,2	9	19,6	37	80,4	53	52,5	5	9,4	48	90,6	0,1414	2,22	0,74	6,64	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8787
Metabolism and nutrition disorders	Decreased appetite	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Decreased appetite	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2390	3,57	0,37	34,32	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Dehydration	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Dehydration	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypercholester olaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1823	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypercholester olaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Metabolism and nutrition disorders	Hypercholesterolaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9316	1,13	0,07	18,05	Convergence criterion (GCONV=1E-8) satisfied.	0,9989
Metabolism and nutrition disorders	Hyperglycaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperglycaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8875	1,22	0,08	19,54	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1738
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypertriglycer- idaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperuricaemia	IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9421	1,09	0,10	12,05	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperuricaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypoglycaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypoglycaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypoglycaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1347	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypomagnesaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypomagnesaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hypophosphatae- mia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8903	1,21	0,08	19,44	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypovolaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypovolaemia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Iron deficiency	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Iron deficiency	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Vitamin D deficiency	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Vitamin D deficiency	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Metabolism and nutrition disorders	Vitamin D deficiency	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIA	31	29,8	7	22,6	24	77,4	33	32,7	6	18,2	27	81,8	0,5763	1,36	0,46	4,06	Convergence criterion (GCONV=1E-8) satisfied.	0,6327
Musculoskeletal and connective tissue disorders		IIB	27	26,0	9	33,3	18	66,7	15	14,9	3	20,0	12	80,0	0,3535	1,84	0,50	6,82	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	15	32,6	31	67,4	53	52,5	8	15,1	45	84,9	0,0142	2,82	1,19	6,71	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	IIA	31	29,8	2	6,5	29	93,5	33	32,7	3	9,1	30	90,9	0,7446	0,74	0,12	4,45	Convergence criterion (GCONV=1E-8) satisfied.	0,2307
Musculoskeletal and connective tissue disorders	Arthralgia	IIB	27	26,0	6	22,2	21	77,8	15	14,9	1	6,7	14	93,3	0,1954	3,68	0,44	30,61	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthralgia	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	1	1,9	52	98,1	0,0507	6,43	0,75	55,12	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Arthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3448
Musculoskeletal and connective tissue disorders	Arthritis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Arthritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,5029	2,22	0,20	24,52	Convergence criterion (GCONV=1E-8) satisfied.	0,2510
Musculoskeletal and connective tissue disorders	Back pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Back pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	4	7,5	49	92,5	0,3268	0,35	0,04	3,16	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2291

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Bone pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Bone pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Coccydynia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Coccydynia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2329
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Musculoskeletal and connective tissue disorders	Dupuytren's contracture	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Limb discomfort	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Limb discomfort	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Muscle spasms	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscle spasms	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscle spasms	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2897	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2561	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	2	3,8	51	96,2	0,2726	2,51	0,46	13,69	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Neck pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Neck pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Osteoarthritis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2464	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9153	1,16	0,07	18,63	Convergence criterion (GCONV=1E-8) satisfied.	0,7135
Musculoskeletal and connective tissue disorders	Pain in extremity	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6754	0,56	0,03	8,92	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Pain in extremity	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4409	2,49	0,23	27,51	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Periarthritis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1967	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Periarthritis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4701	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Spinal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Spinal pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders	Spinal pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Synovial cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Synovial cyst	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Tendonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Tendonitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	1	3,2	30	96,8	33	32,7	3	9,1	30	90,9	0,3820	0,38	0,04	3,64	Convergence criterion (GCONV=1E-8) satisfied.	0,2091
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2873	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,3671	2,90	0,26	32,43	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders		IIA	31	29,8	8	25,8	23	74,2	33	32,7	7	21,2	26	78,8	0,5871	1,32	0,48	3,65	Convergence criterion (GCONV=1E-8) satisfied.	0,8438
Nervous system disorders		IIB	27	26,0	7	25,9	20	74,1	15	14,9	3	20,0	12	80,0	0,5502	1,51	0,39	5,83	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	11	23,9	35	76,1	53	52,5	13	24,5	40	75,5	0,9949	1,00	0,45	2,24	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Arachnoid cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Arachnoid cyst	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral arteriosclerosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral arteriosclerosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cognitive disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cognitive disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cognitive disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Disturbance in attention	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Disturbance in attention	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Dizziness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1640
Nervous system disorders	Dizziness	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dizziness	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4387	2,50	0,23	27,58	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Dysaesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Dysaesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Encephalopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Encephalopathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Headache	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,8858	1,15	0,16	8,20	Convergence criterion (GCONV=1E-8) satisfied.	0,4492
Nervous system disorders	Headache	IIB	27	26,0	1	3,7	26	96,3	15	14,9	2	13,3	13	86,7	0,2666	0,28	0,03	3,09	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Headache	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4829	2,31	0,21	25,53	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Hypoaesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Hypoaesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Lethargy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Lethargy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Loss of consciousness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Memory impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Memory impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Migraine	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Migraine	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Myelopathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Myelopathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Myelopathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	IIA	31	29,8	4	12,9	27	87,1	33	32,7	0	0,0	33	100,0	0,0311	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2476
Nervous system disorders	Neuropathy peripheral	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neuropathy peripheral	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8656	1,27	0,08	20,37	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Neurotoxicity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Neurotoxicity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4131
Nervous system disorders	Paraesthesia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	4	7,5	49	92,5	0,2595	0,30	0,03	2,72	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3074	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Parosmia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Parosmia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,8280
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4492	2,45	0,22	27,04	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Polyneuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Seizure	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Seizure	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Somnolence	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3456
Nervous system disorders	Somnolence	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Somnolence	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,9044	1,18	0,07	18,95	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3485	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Tension headache	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Tension headache	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Transient ischaemic attack	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Transient ischaemic attack	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Transient ischaemic attack	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Upper motor neurone lesion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Upper motor neurone lesion	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2650	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Vocal cord paralysis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Vocal cord paralysis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,7699	1,34	0,19	9,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9168
Psychiatric disorders		IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9086	1,15	0,10	12,70	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	2	3,8	51	96,2	0,4652	1,93	0,32	11,54	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,0733	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Anxiety	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Anxiety	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2433	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Depressed mood	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depressed mood	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Psychiatric disorders	Depression	IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,8866	1,22	0,08	19,56	Convergence criterion (GCONV=1E-8) satisfied.	0,9992
Psychiatric disorders	Depression	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Depression	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8603	1,28	0,08	20,50	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Insomnia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Insomnia	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1090	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Mental status changes	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Mental status changes	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Psychiatric disorders	Psychiatric symptom	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Psychiatric symptom	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Psychiatric symptom	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3833	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Psychiatric disorders	Sleep disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	Sleep disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	1	3,0	32	97,0	0,9458	1,10	0,07	18,02	Convergence criterion (GCONV=1E-8) satisfied.	0,7246
Renal and urinary disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	4	8,7	42	91,3	53	52,5	3	5,7	50	94,3	0,4702	1,73	0,39	7,73	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Renal and urinary disorders	Acute kidney injury	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Acute kidney injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Acute kidney injury	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Dysuria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Dysuria	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	1	1,9	52	98,1	0,8585	1,29	0,08	20,62	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Lower urinary tract symptoms	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Lower urinary tract symptoms	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Lower urinary tract symptoms	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Micturition disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Micturition disorder	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3827	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Pollakiuria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Pollakiuria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Proteinuria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Proteinuria	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Proteinuria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal cyst	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal cyst	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Renal impairment	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Renal impairment	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Urinary tract pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Urinary tract pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Urinary tract pain	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2339
Reproductive system and breast disorders		IIB	27	26,0	2	7,4	25	92,6	15	14,9	1	6,7	14	93,3	0,9779	1,03	0,09	11,43	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Balanoposthitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Balanoposthitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Reproductive system and breast disorders	Breast discharge	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast discharge	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast discharge	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Breast pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Breast pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Reproductive system and breast disorders	Gynaecomastia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Gynaecomastia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4617	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Gynaecomastia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	13	41,9	18	58,1	33	32,7	7	21,2	26	78,8	0,0717	2,28	0,91	5,72	Convergence criterion (GCONV=1E-8) satisfied.	0,1595
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	4	14,8	23	85,2	15	14,9	4	26,7	11	73,3	0,3134	0,50	0,12	1,99	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	14	30,4	32	69,6	53	52,5	9	17,0	44	83,0	0,0350	2,50	1,04	6,02	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Catarrh	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Catarrh	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Cough	IIA	31	29,8	6	19,4	25	80,6	33	32,7	4	12,1	29	87,9	0,4015	1,71	0,48	6,06	Convergence criterion (GCONV=1E-8) satisfied.	0,4808
Respiratory, thoracic and mediastinal disorders	Cough	IIB	27	26,0	2	7,4	25	92,6	15	14,9	2	13,3	13	86,7	0,5213	0,53	0,07	3,78	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Cough	IIIA	46	44,2	7	15,2	39	84,8	53	52,5	4	7,5	49	92,5	0,1264	2,63	0,73	9,54	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3657	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dysphonia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	5	16,1	26	83,9	33	32,7	0	0,0	33	100,0	0,0144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0034
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	2	13,3	13	86,7	0,0582	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	3	5,7	50	94,3	0,6069	1,53	0,30	7,86	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4602	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Haemoptysis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0988
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6856	0,57	0,04	9,09	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1166	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleurisy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0669	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0495	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Productive cough	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0590	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Productive cough	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Productive cough	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rales	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rales	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1290	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1349	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1139	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3771	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders		IIA	31	29,8	11	35,5	20	64,5	33	32,7	2	6,1	31	93,9	0,0028	7,19	1,59	32,49	Convergence criterion (GCONV=1E-8) satisfied.	0,6752
Skin and subcutaneous tissue disorders		IIB	27	26,0	5	18,5	22	81,5	15	14,9	1	6,7	14	93,3	0,2700	3,14	0,37	26,90	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	20	43,5	26	56,5	53	52,5	3	5,7	50	94,3	<.0001	10,43	3,09	35,18	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Actinic keratosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Actinic keratosis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3324	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2995
Skin and subcutaneous tissue disorders	Alopecia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Alopecia	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2147	3,79	0,39	36,51	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Dermatitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3785	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2827	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis acneiform	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1204	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2498	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Drug eruption	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Drug eruption	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4795	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Drug eruption	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2689	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Dry skin	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Dry skin	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1036	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Erythema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Erythema	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1177	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Miliaria	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Miliaria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Miliaria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Onychoclasia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Onychoclasia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Papule	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Papule	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0623	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3522
Skin and subcutaneous tissue disorders	Pruritus	IIB	27	26,0	3	11,1	24	88,9	15	14,9	1	6,7	14	93,3	0,6201	1,76	0,18	16,91	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Pruritus	IIIA	46	44,2	6	13,0	40	87,0	53	52,5	1	1,9	52	98,1	0,0211	8,10	0,97	67,31	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0,0	33	100,0	0,0676	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0,0	53	100,0	0,0262	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash erythematous	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash erythematous	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash maculo-papular	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash pruritic	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash pruritic	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash pruritic	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Scar pain	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Scar pain	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin burning sensation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin burning sensation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2537	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Skin exfoliation	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Skin exfoliation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Skin exfoliation	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Toxic skin eruption	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Urticaria	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Urticaria	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Skin and subcutaneous tissue disorders	Vitiligo	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2909	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Vitiligo	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Vitiligo	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Surgical and medical procedures	Cancer surgery	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Surgical and medical procedures	Cancer surgery	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders		IIA	31	29,8	2	6,5	29	93,5	33	32,7	1	3,0	32	97,0	0,5011	2,23	0,20	24,60	Convergence criterion (GCONV=1E-8) satisfied.	0,7119
Vascular disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	1	6,7	14	93,3	0,6892	0,57	0,04	9,15	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	3	5,7	50	94,3	0,8446	0,84	0,14	5,01	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hot flush	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1662	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hot flush	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	2	6,5	29	93,5	33	32,7	0	0,0	33	100,0	0,1280	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypotension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypotension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypotension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Orthostatic hypotension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Orthostatic hypotension	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Vascular disorders	Phlebitis superficial	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Phlebitis superficial	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Phlebitis superficial	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Vascular stenosis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Vascular stenosis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

All

		Atezolizumab (N=104)							Best Supportive Care(BSC) (N=101)							Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored			Patients		Patients with Event		Censored			log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)	
Blood and lymphatic system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Blood and lymphatic system disorders	Thrombocytopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE	
Eye disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5720	0,51	0,05	5,59	Convergence criterion (GCONV=1E-8) satisfied.	NE	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9964	0,99	0,06	15,88	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5647	2,00	0,18	22,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Pyrexia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3001	3,11	0,32	29,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0278	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	3	3,0	98	97,0	0,9911	0,99	0,20	4,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3266	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1546	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight increased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0,0	101	100,0	0,0234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphataemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,4748	2,36	0,21	26,46	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	4	4,0	97	96,0	0,4177	0,50	0,09	2,74	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9941	1,01	0,06	16,16	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1788	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4932	0,44	0,04	4,88	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9321	0,89	0,06	14,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3839
General disorders and administrative site conditions		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7843	1,47	0,09	23,51	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administrative site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administrative site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3765	2,67	0,28	25,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Infections and infestations		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6411	1,76	0,16	19,37	Convergence criterion (GCONV=1E-8) satisfied.	0,6036
Investigations		Female	22	21,2	1	4,5	21	95,5	30	29,7	2	6,7	28	93,3	0,7534	0,68	0,06	7,53	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gamma-glutamyltransferase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	2	6,7	28	93,3	0,2322	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Weight increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Investigations	Weight increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1793	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,5484	2,06	0,18	23,09	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	3	4,2	68	95,8	0,2491	0,29	0,03	2,76	Convergence criterion (GCONV=1E-8) satisfied.	0,3594
Nervous system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7548	1,55	0,10	24,94	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1295
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Skin and subcutaneous tissue disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0778	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders	Hypertension	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:47

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1493	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Blood and lymphatic system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3160
Eye disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9913	1,02	0,06	16,24	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9732	1,05	0,07	16,77	Convergence criterion (GCONV=1E-8) satisfied.	0,3159
General disorders and administration site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5249	2,14	0,19	23,59	Convergence criterion (GCONV=1E-8) satisfied.	0,4248

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Infections and infestations		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infctions and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	2	3,1	62	96,9	62	61,4	3	4,8	59	95,2	0,6577	0,67	0,11	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,2112
Investigations		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gamma-glutamyltransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	2	3,2	60	96,8	0,1595	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Weight increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	4	6,3	60	93,8	62	61,4	0	0,0	62	100,0	0,0395	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1673	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9970	0,99	0,06	15,91	Convergence criterion (GCONV=1E-8) satisfied.	0,3080
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	3	4,8	59	95,2	0,3227	0,34	0,04	3,24	Convergence criterion (GCONV=1E-8) satisfied.	0,5524
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9961	0,99	0,06	15,92	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0943
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypertension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System	MedDRA Organ Class	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9033	0,84	0,05	13,47	Convergence criterion (GCONV=1E-8) satisfied.	0,6434
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2793
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5370	2,09	0,19	23,09	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4765
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9791	1,04	0,06	16,59	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infestations and infections		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infestations and infections		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	2	8,7	21	91,3	0,4260	0,39	0,04	4,31	Convergence criterion (GCONV=1E-8) satisfied.	0,5942
Investigations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5413	2,08	0,19	22,93	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3634	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Weight increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1453	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6157
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9817	1,03	0,06	16,52	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,8862	0,82	0,05	13,07	Convergence criterion (GCONV=1E-8) satisfied.	0,8955
Nervous system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	3	4,4	65	95,6	0,3646	0,37	0,04	3,52	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2393
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1403	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:47

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3-5 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1552
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2053	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2558
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administrative site conditions		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4371	2,51	0,23	27,69	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Pyrexia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administrative site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0949
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0466	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0213	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0495	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	2	6,1	31	93,9	0,1755	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1344
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2317	3,63	0,38	34,95	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0,0	53	100,0	0,0103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyce ridaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglyce ridaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyce ridaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1705
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6175
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	3	5,7	50	94,3	0,8201	0,81	0,14	4,87	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1661
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

All

		Atezolizumab (N=104)							Best Supportive Care(BSC) (N=101)							Atezolizumab vs. Best Supportive Care(BSC)						
		Patients		Patients with Event		Censored			Patients		Patients with Event		Censored			log-rank	Hazard Ratio				Interac-tion Test	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)		
Blood and lymphatic system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Blood and lymphatic system disorders	Leukopenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Blood and lymphatic system disorders	Neutropenia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Blood and lymphatic system disorders	Thrombocytope nia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,2963	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Eye disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	2	2,0	99	98,0	0,5720	0,51	0,05	5,59	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Eye disorders	Cataract	n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9964	0,99	0,06	15,88	Convergence criterion (GCONV=1E-8) satisfied.	NE		
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE		

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Colitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,5647	2,00	0,18	22,02	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Fatigue	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Influenza like illness	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administrative site conditions	Pyrexia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	1	1,0	100	99,0	0,3001	3,11	0,32	29,91	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3143	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3144	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1426	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0278	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,0475	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Kidney infection	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6573	1,50	0,25	8,95	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Alanine aminotransferase increased	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1580	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Aspartate aminotransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3266	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3035	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Weight increased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	0	0,0	101	100,0	0,0826	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hyperkalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypocalcaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypophosphataemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Muscular weakness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3115	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3088	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	2	1,9	102	98,1	101	100,0	1	1,0	100	99,0	0,4748	2,36	0,21	26,46	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,1957	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	2	2,0	99	98,0	0,9979	1,00	0,14	7,08	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3197	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3274	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Post herpetic neuralgia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Syncope	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Renal and urinary disorders	Chronic kidney disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Reproductive system and breast disorders	Genital rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Parapsoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3008	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Rash	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Vascular disorders	Hypertension	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1788	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Leukopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Neutropenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3350	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Thrombocytopenia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4932	0,44	0,04	4,88	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9321	0,89	0,06	14,17	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Eye disorders	Cataract	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Gastrointestinal disorders	Colitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3839
General disorders and administrative site conditions		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7843	1,47	0,09	23,51	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Fatigue	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
General disorders and administrative site conditions	Fatigue	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administrative site conditions	Influenza like illness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
General disorders and administrative site conditions	Influenza like illness	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4187	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administrative site conditions	Pyrexia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
General disorders and administrative site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	3	3,7	79	96,3	71	70,3	1	1,4	70	98,6	0,3765	2,67	0,28	25,65	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1781	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Infections and infestations		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,0752	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9959
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Kidney infection	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,6411	1,76	0,16	19,37	Convergence criterion (GCONV=1E-8) satisfied.	0,9230
Investigations		Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,8274	1,36	0,08	21,76	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3476	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gamma-glutamyltransferase increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2881	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Investigations	Weight increased	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1830	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9974
Metabolism and nutrition disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypocalcaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Metabolism and nutrition disorders	Hypophosphataemia	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2207	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1793	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Musculoskeletal and connective tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3444	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Muscular weakness	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3440	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Musculoskeletal and connective tissue disorders	Myalgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	2	2,4	80	97,6	71	70,3	1	1,4	70	98,6	0,5484	2,06	0,18	23,09	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2845	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,2340	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4842	0,43	0,04	4,80	Convergence criterion (GCONV=1E-8) satisfied.	0,1281
Nervous system disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2936	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2996	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Post herpetic neuralgia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3533	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Nervous system disorders	Syncope	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Renal and urinary disorders	Chronic kidney disease	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Reproductive system and breast disorders	Genital rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4028	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
Skin and subcutaneous tissue disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0778	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Parapsoriasis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,1840	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Skin and subcutaneous tissue disorders	Rash	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Vascular disorders		Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypertension	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2253	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:52

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1493	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Blood and lymphatic system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Leukopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Neutropenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2959	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Thrombocytopenia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3160
Eye disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	1	2,6	38	97,4	0,9913	1,02	0,06	16,24	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0985
Eye disorders	Cataract	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders	Colitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Colitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9732	1,05	0,07	16,77	Convergence criterion (GCONV=1E-8) satisfied.	0,3159
General disorders and administration site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Fatigue	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	1	1,6	61	98,4	0,5249	2,14	0,19	23,59	Convergence criterion (GCONV=1E-8) satisfied.	0,4248
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3268	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3404	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	96,9	62	61,4	0	0,0	62	100,0	0,1408	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9951
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9975
Infections and infestations		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,0522	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9973
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,0679	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Kidney infection	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9963	1,00	0,14	7,13	Convergence criterion (GCONV=1E-8) satisfied.	0,2779
Investigations		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Gamma-glutamyltransferase increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations	Weight increased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9964
Metabolism and nutrition disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hyperkalaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypocalcaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3032	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypophosphataemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1673	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Muscular weakness	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3329	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Musculoskeletal and connective tissue disorders	Myalgia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3324	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	63	98,4	62	61,4	1	1,6	61	98,4	0,9970	0,99	0,06	15,91	Convergence criterion (GCONV=1E-8) satisfied.	0,3080
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9967

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,1797	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	2	3,2	60	96,8	0,5649	0,50	0,05	5,53	Convergence criterion (GCONV=1E-8) satisfied.	0,1903
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3212	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3214	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Post herpetic neuralgia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3387	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Post herpetic neuralgia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Syncope	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Renal and urinary disorders	Chronic kidney disease	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Reproductive system and breast disorders	Genital rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Skin and subcutaneous tissue disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,2951	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Parapsoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders	Rash	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Vascular disorders	Hypertension	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System	MedDRA	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Organ Class	Preferred Term																			

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:52

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Blood and lymphatic system disorders	Neutropenia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Neutropenia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9033	0,84	0,05	13,47	Convergence criterion (GCONV=1E-8) satisfied.	0,6434
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3648	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2793
Eye disorders	Cataract	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2712	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5370	2,09	0,19	23,09	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
General disorders and administration site conditions	Influenza like illness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4765
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9791	1,04	0,06	16,59	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3264	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3085	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1911	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1448	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,0614	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	Asia Pacific and Austral- ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Kidney infection	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Asia Pacific and Austral ia	29	27,9	1	3,4	28	96,6	23	22,8	2	8,7	21	91,3	0,4260	0,39	0,04	4,31	Convergence criterion (GCONV=1E-8) satisfied.	0,1765
Investigations		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Alanine aminotransferase increased	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1474	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Aspartate aminotransferase increased	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3634	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2699	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight increased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1453	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Metabolism and nutrition disorders	Hyperkalaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3125	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Musculoskeletal and connective tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Myalgia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3000	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,6157
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9817	1,03	0,06	16,52	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2850	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4757
Nervous system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	2	2,9	66	97,1	0,6116	0,54	0,05	5,98	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3444	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Post herpetic neuralgia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3657	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2986	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Reproductive system and breast disorders	Genital rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America	10	9,6	0	0,0	10	100,0	10	9,9	1	10,0	9	90,0	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0,0	68	100,0	0,1403	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Parapsoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2879	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Time to First Grade 3 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Leukopenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Leukopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	Neutropenia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Neutropenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Thrombocytopenia	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Thrombocytopenia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1552
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	2	3,8	51	96,2	0,2053	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Cataract	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2558
Eye disorders	Cataract	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Cataract	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3600	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3882	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2899	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4371	2,51	0,23	27,69	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Fatigue	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Fatigue	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Influenza like illness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Influenza like illness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Influenza like illness	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3794	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0949

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0466	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2553	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0213	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,0495	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Kidney infection	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Kidney infection	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2761	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,3093
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	1	1,9	52	98,1	0,2317	3,63	0,38	34,95	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Alanine aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Alanine aminotransferase increased	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1233	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Aspartate aminotransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Aspartate aminotransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2822	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Gamma-glutamyltransferase increased	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Weight increased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3404	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Weight increased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Weight increased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0519	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hyperkalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hyperkalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypocalcaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypocalcaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypophosphataemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypophosphataemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypophosphataemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2577	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1005	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Muscular weakness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Muscular weakness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	Muscular weakness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Musculoskeletal and connective tissue disorders	Myalgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	Myalgia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2500	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1705
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4561	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	2	3,8	51	96,2	0,8558	1,20	0,17	8,52	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2824	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3711	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Post herpetic neuralgia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Post herpetic neuralgia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Syncope	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Syncope	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Renal and urinary disorders	Chronic kidney disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Renal and urinary disorders	Chronic kidney disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	Chronic kidney disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2770	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Reproductive system and breast disorders	Genital rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	Genital rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIB	27	26,0	0	0,0	27	100,0	15	14,9	1	6,7	14	93,3	0,1880	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Parapsoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Parapsoriasis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Rash	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Rash	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Vascular disorders	Hypertension	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Vascular disorders	Hypertension	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Vascular disorders	Hypertension	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2593	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:52

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CI	95% Upper CI	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Investigations	Neutrophil count decreased	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3111	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1520	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	2	2,0	99	98,0	0,1676	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Brain oedema	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3384	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3098	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_se_tte_soc.sas
 Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_se_tte_soc_sg_9TGR4AE_EGFRALKKOUK_SP26393_9T23_SE_18APR2022_29527_x1s
 27JUN2022 17:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Investigations		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,3938	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1775	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Metabolism and nutrition disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypertriglyceridaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3345	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Metabolism and nutrition disorders	Hypokalaemia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	Female	22	21,2	0	0,0	22	100,0	30	29,7	1	3,3	29	96,7	0,4516	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2866	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Investigations		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3224	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations	Neutrophil count decreased	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
Metabolism and nutrition disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3122	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypertriglyceridaemia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Metabolism and nutrition disorders	Hypokalaemia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,2974	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
Nervous system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Brain oedema	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3378	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3356	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3042	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System	MedDRA Organ Class	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3221	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0,0	23	100,0	0,1884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3683	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypertriglyceridaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3482	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3576	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2819	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Grade 4 Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Investigations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3447	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Investigations	Neutrophil count decreased	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	Neutrophil count decreased	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0,0	53	100,0	0,1104	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypertriglyceridaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Metabolism and nutrition disorders	Hypokalaemia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	Hypokalaemia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2513	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Brain oedema	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Brain oedema	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Brain oedema	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3914	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3437	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2695	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Blood and lymphatic system disorders	Sarcoidosis of lymph node	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3123	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Endocrine disorders	Inappropriate antidiuretic hormone secretion	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3226	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Eye disorders	Vitreous haemorrhage	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3226	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders		n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Gastrointestinal disorders	Abdominal hernia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
General disorders and administration site conditions	Pyrexia	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9807	1,03	0,06	16,54	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Cholestasis	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3202	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3066	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Immune system disorders	Hypersensitivity	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations		n/a	104	100,0	7	6,7	97	93,3	101	100,0	0	0,0	101	100,0	0,0083	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Cellulitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Pneumonia	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia pneumococcal	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3268	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Sepsis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Infections and infestations	Tonsillitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	1	1,0	103	99,0	101	100,0	1	1,0	100	99,0	0,9713	0,95	0,06	15,20	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3021	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3235	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders		n/a	104	100,0	3	2,9	101	97,1	101	100,0	2	2,0	99	98,0	0,6492	1,51	0,25	9,04	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebellar infarction	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Cerebral infarction	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3039	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Demyelinating polyneuropathy	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Loss of consciousness	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3145	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Paraesthesia	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3102	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Nervous system disorders	Peripheral sensory neuropathy	n/a	104	100,0	0	0,0	104	100,0	101	100,0	1	1,0	100	99,0	0,3149	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0,0	101	100,0	0,1635	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders		n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3198	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
Skin and subcutaneous tissue disorders	Psoriasis	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0,0	101	100,0	0,3198	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3442	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders	Atrial fibrillation	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2817	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2817	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Eye disorders	Vitreous haemorrhage	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Gastrointestinal disorders	Abdominal hernia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1868	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions	Pyrexia	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1868	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
General disorders and administration site conditions	Pyrexia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9254	0,88	0,05	14,00	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Hepatobiliary disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Hepatobiliary disorders	Cholestasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders																				
Infections and infestations		Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0,0	71	100,0	0,0607	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Infections and infestations		Female	22	21,2	3	13,6	19	86,4	30	29,7	0	0,0	30	100,0	0,0383	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Cellulitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3555	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Pneumonia pneumococcal	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Infections and infestations	Sepsis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Tonsillitis	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Infections and infestations	Tonsillitis	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	1	1,2	81	98,8	71	70,3	1	1,4	70	98,6	0,9052	0,85	0,05	13,51	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	2	2,8	69	97,2	0,4863	0,44	0,04	4,82	Convergence criterion (GCONV=1E-8) satisfied.	0,0466
Nervous system disorders		Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0,0	30	100,0	0,0861	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2871	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9969
Nervous system disorders	Cerebellar infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3462	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebral infarction	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Demyelinating polyneuropathy	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0,0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Nervous system disorders	Loss of consciousness	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0,0	30	100,0	0,2076	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2825	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Paraesthesia	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Male	82	78,8	0	0,0	82	100,0	71	70,3	1	1,4	70	98,6	0,2842	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9968
Nervous system disorders	Peripheral sensory neuropathy	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0,0	71	100,0	0,1886	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3521	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
Skin and subcutaneous tissue disorders		Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0,0	71	100,0	0,3505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Psoriasis	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0,0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Serious Adverse Event

MODEL: Unstratified analysis

STUDY: GO29527

Time to Event Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Blood and lymphatic system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3132	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Blood and lymphatic system disorders	Sarcoidosis of lymph node	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3251	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3251	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Cardiac disorders	Atrial fibrillation	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Endocrine disorders	Inappropriate antidiuretic hormone secretion	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Eye disorders	Vitreous haemorrhage	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Eye disorders	Vitreous haemorrhage	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Gastrointestinal disorders	Abdominal hernia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
General disorders and administration site conditions	Pyrexia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
General disorders and administration site conditions	Pyrexia	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,0993
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3311	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Cholestasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Immune system disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders																				
Infections and infestations		< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0,0	62	100,0	0,0857	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9976
Infections and infestations		>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0480	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Cellulitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Pneumonia pneumococcal	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Sepsis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Infections and infestations	Tonsillitis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Infections and infestations	Tonsillitis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3074	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,1006
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3074	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		< 65	64	61,5	2	3,1	62	96,9	62	61,4	2	3,2	60	96,8	0,9991	1,00	0,14	7,09	Convergence criterion (GCONV=1E-8) satisfied.	0,2777
Nervous system disorders		>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Cerebellar infarction	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Cerebral infarction	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Demyelinating polyneuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3037	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Loss of consciousness	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3096	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Paraesthesia	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	< 65	64	61,5	0	0,0	64	100,0	62	61,4	1	1,6	61	98,4	0,3173	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Nervous system disorders	Peripheral sensory neuropathy	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0,0	39	100,0	0,1627	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0,0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0,0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
Skin and subcutaneous tissue disorders		>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0,0	62	100,0	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Skin and subcutaneous tissue disorders	Psoriasis	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0,0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 18:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Cardiac disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Endocrine disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2733	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Eye disorders	Vitreous haemorrhage	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
General disorders and administration site conditions		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	1	1,5	67	98,5	0,9507	1,09	0,07	17,46	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3261	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations		Europe and Middle East	65	62,5	5	7,7	60	92,3	68	67,3	0	0,0	68	100,0	0,0203	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Cellulitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Meningitis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3100	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Infections and infestations	Pneumonia pneumococcal	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sepsis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Tonsillitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2343

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3126	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3126	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2888	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	1	4,3	22	95,7	0,9218	0,87	0,05	13,92	Convergence criterion (GCONV=1E-8) satisfied.	0,8790
Nervous system disorders		Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	1	1,5	67	98,5	0,5420	2,08	0,19	22,89	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Cerebellar infarction	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	1	4,3	22	95,7	0,2835	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Demyelinating polyneuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3042	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3282	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Nervous system disorders	Peripheral sensory neuropathy	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	1	1,5	67	98,5	0,3364	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0,0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0,0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2983	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0,0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0,0	68	100,0	0,2983	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Skin and subcutaneous tissue disorders	Psoriasis	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas

Output: root/clinical_studies/R05541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 18:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Serious Adverse Event
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4386	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Cardiac disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	Inappropriate antidiuretic hormone secretion	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3749	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	Vitreous haemorrhage	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Eye disorders	Vitreous haemorrhage	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Eye disorders	Vitreous haemorrhage	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3749	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Gastrointestinal disorders	Abdominal hernia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	Abdominal hernia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3847	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
General disorders and administration site conditions		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
General disorders and administration site conditions	Pyrexia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	Pyrexia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2296

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Hepatobiliary disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Cholestasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Cholestasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Immune system disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders																				
Infections and infestations		IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations		IIIA	46	44,2	7	15,2	39	84,8	53	52,5	0	0,0	53	100,0	0,0034	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Cellulitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Cellulitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Pneumonia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Pneumonia pneumococcal	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Pneumonia pneumococcal	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2877	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Infections and infestations	Sepsis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Sepsis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Infections and infestations	Tonsillitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	Tonsillitis	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2394
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3352	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2746	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders		IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2861
Nervous system disorders		IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders		IIIA	46	44,2	2	4,3	44	95,7	53	52,5	1	1,9	52	98,1	0,4703	2,36	0,21	26,02	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	1	3,0	32	97,0	0,3519	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebellar infarction	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebellar infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Cerebral infarction	IIB	27	26,0	1	3,7	26	96,3	15	14,9	0	0,0	15	100,0	0,4543	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Cerebral infarction	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac-tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli-hood ratio)
Nervous system disorders	Demyelinating polyneuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Demyelinating polyneuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Demyelinating polyneuropathy	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Loss of consciousness	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Loss of consciousness	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2568	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Paraesthesia	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Paraesthesia	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3515	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Nervous system disorders	Peripheral sensory neuropathy	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Nervous system disorders	Peripheral sensory neuropathy	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	Peripheral sensory neuropathy	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	1	1,9	52	98,1	0,3482	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0,0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0,0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders		IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders		IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0,0	33	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
Skin and subcutaneous tissue disorders	Psoriasis	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	Psoriasis	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0,0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interac- tion Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likeli- hood ratio)

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

Zum Behandlungsabbruch führende unerwünschte Ereignisse nach SOC/PT (deskriptiv)

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	n/a	104	100,0	1	1,0	101	100,0	0	0
Cardiac disorders		n/a	104	100,0	2	1,9	101	100,0	0	0
Cardiac disorders	Atrial fibrillation	n/a	104	100,0	1	1,0	101	100,0	0	0
Cardiac disorders	Cardiac failure	n/a	104	100,0	1	1,0	101	100,0	0	0
Endocrine disorders		n/a	104	100,0	2	1,9	101	100,0	0	0
Endocrine disorders	Hypothyroidism	n/a	104	100,0	2	1,9	101	100,0	0	0
Gastrointestin al disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Gastrointestin al disorders	Colitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	100,0	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0
Immune system disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Immune system disorders	Hypersensitivi ty	n/a	104	100,0	1	1,0	101	100,0	0	0
Infections and infestations		n/a	104	100,0	2	1,9	101	100,0	0	0
Infections and infestations	Encephalitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Infections and infestations	Meningitis	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations		n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Alanine aminotransfera se increased	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations	Aspartate aminotransfera se increased	n/a	104	100,0	1	1,0	101	100,0	0	0
Investigations	Blood creatinine increased	n/a	104	100,0	1	1,0	101	100,0	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	104	100,0	1	1,0	101	100,0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders		n/a	104	100,0	5	4,8	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	n/a	104	100,0	1	1,0	101	100,0	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	104	100,0	3	2,9	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Blood and lymphatic system disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Male	82	78,8	1	1,2	71	70,3	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Female	22	21,2	0	0,0	30	29,7	0	0
Cardiac disorders		Male	82	78,8	2	2,4	71	70,3	0	0
Cardiac disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Cardiac disorders	Atrial fibrillation	Male	82	78,8	1	1,2	71	70,3	0	0
Cardiac disorders	Atrial fibrillation	Female	22	21,2	0	0,0	30	29,7	0	0
Cardiac disorders	Cardiac failure	Male	82	78,8	1	1,2	71	70,3	0	0
Cardiac disorders	Cardiac failure	Female	22	21,2	0	0,0	30	29,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Endocrine disorders		Male	82	78,8	2	2,4	71	70,3	0	0
Endocrine disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Endocrine disorders	Hypothyroidism	Male	82	78,8	2	2,4	71	70,3	0	0
Endocrine disorders	Hypothyroidism	Female	22	21,2	0	0,0	30	29,7	0	0
Gastrointestin al disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Gastrointestin al disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Gastrointestin al disorders	Colitis	Male	82	78,8	1	1,2	71	70,3	0	0
Gastrointestin al disorders	Colitis	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders		Male	82	78,8	3	3,7	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0
Immune system disorders		Male	82	78,8	1	1,2	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Immune system disorders	Hypersensitivity	Male	82	78,8	1	1,2	71	70,3	0	0
Immune system disorders	Hypersensitivity	Female	22	21,2	0	0,0	30	29,7	0	0
Infections and infestations		Male	82	78,8	0	0,0	71	70,3	0	0
Infections and infestations		Female	22	21,2	2	9,1	30	29,7	0	0
Infections and infestations	Encephalitis	Male	82	78,8	0	0,0	71	70,3	0	0
Infections and infestations	Encephalitis	Female	22	21,2	1	4,5	30	29,7	0	0
Infections and infestations	Meningitis	Male	82	78,8	0	0,0	71	70,3	0	0
Infections and infestations	Meningitis	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations		Male	82	78,8	1	1,2	71	70,3	0	0
Investigations		Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Alanine aminotransferase increased	Male	82	78,8	0	0,0	71	70,3	0	0
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Aspartate aminotransfera se increased	Male	82	78,8	0	0,0	71	70,3	0	0
Investigations	Aspartate aminotransfera se increased	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Blood creatinine increased	Male	82	78,8	1	1,2	71	70,3	0	0
Investigations	Blood creatinine increased	Female	22	21,2	0	0,0	30	29,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	82	78,8	1	1,2	71	70,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	22	21,2	0	0,0	30	29,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Male	82	78,8	1	1,2	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders		Male	82	78,8	5	6,1	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	82	78,8	1	1,2	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Male	82	78,8	1	1,2	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Female	22	21,2	0	0,0	30	29,7	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	82	78,8	3	3,7	71	70,3	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	22	21,2	0	0,0	30	29,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		< 65	64	61,5	1	1,6	62	61,4	0	0
Blood and lymphatic system disorders		\geq 65	40	38,5	0	0,0	39	38,6	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	< 65	64	61,5	1	1,6	62	61,4	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	\geq 65	40	38,5	0	0,0	39	38,6	0	0
Cardiac disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders		\geq 65	40	38,5	2	5,0	39	38,6	0	0
Cardiac disorders	Atrial fibrillation	< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders	Atrial fibrillation	\geq 65	40	38,5	1	2,5	39	38,6	0	0
Cardiac disorders	Cardiac failure	< 65	64	61,5	0	0,0	62	61,4	0	0
Cardiac disorders	Cardiac failure	\geq 65	40	38,5	1	2,5	39	38,6	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Endocrine disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Endocrine disorders		>= 65	40	38,5	0	0,0	39	38,6	0	0
Endocrine disorders	Hypothyroidis m	< 65	64	61,5	2	3,1	62	61,4	0	0
Endocrine disorders	Hypothyroidis m	>= 65	40	38,5	0	0,0	39	38,6	0	0
Gastrointesti nal disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Gastrointesti nal disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Gastrointesti nal disorders	Colitis	< 65	64	61,5	0	0,0	62	61,4	0	0
Gastrointesti nal disorders	Colitis	>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders	Hepatic function abnormal	>= 65	40	38,5	0	0,0	39	38,6	0	0
Immune system disorders		< 65	64	61,5	1	1,6	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders		>= 65	40	38,5	0	0,0	39	38,6	0	0
Immune system disorders	Hypersensitivity	< 65	64	61,5	1	1,6	62	61,4	0	0
Immune system disorders	Hypersensitivity	>= 65	40	38,5	0	0,0	39	38,6	0	0
Infections and infestations		< 65	64	61,5	1	1,6	62	61,4	0	0
Infections and infestations		>= 65	40	38,5	1	2,5	39	38,6	0	0
Infections and infestations	Encephalitis	< 65	64	61,5	1	1,6	62	61,4	0	0
Infections and infestations	Encephalitis	>= 65	40	38,5	0	0,0	39	38,6	0	0
Infections and infestations	Meningitis	< 65	64	61,5	0	0,0	62	61,4	0	0
Infections and infestations	Meningitis	>= 65	40	38,5	1	2,5	39	38,6	0	0
Investigations		< 65	64	61,5	2	3,1	62	61,4	0	0
Investigations		>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Alanine aminotransferase increased	< 65	64	61,5	1	1,6	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Alanine aminotransfer ase increased	>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Aspartate aminotransfer ase increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Aspartate aminotransfer ase increased	>= 65	40	38,5	0	0,0	39	38,6	0	0
Investigations	Blood creatinine increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Blood creatinine increased	>= 65	40	38,5	0	0,0	39	38,6	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		< 65	64	61,5	1	1,6	62	61,4	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>= 65	40	38,5	0	0,0	39	38,6	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	< 65	64	61,5	1	1,6	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	>= 65	40	38,5	0	0,0	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders		>= 65	40	38,5	3	7,5	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	< 65	64	61,5	0	0,0	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	>= 65	40	38,5	1	2,5	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	< 65	64	61,5	1	1,6	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	>= 65	40	38,5	0	0,0	39	38,6	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	< 65	64	61,5	1	1,6	62	61,4	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	>= 65	40	38,5	2	5,0	39	38,6	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Blood and lymphatic system disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Blood and lymphatic system disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Cardiac disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Cardiac disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Cardiac disorders	Atrial fibrillation	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Cardiac disorders	Atrial fibrillation	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Cardiac disorders	Atrial fibrillation	North America	10	9,6	0	0,0	10	9,9	0	0
Cardiac disorders	Cardiac failure	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Cardiac disorders	Cardiac failure	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Cardiac disorders	Cardiac failure	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Endocrine disorders		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Endocrine disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Endocrine disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Endocrine disorders	Hypothyroidism	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Endocrine disorders	Hypothyroidism	Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Endocrine disorders	Hypothyroidism	North America	10	9,6	0	0,0	10	9,9	0	0
Gastrointestin al disorders		Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Gastrointestin al disorders		Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Gastrointestin al disorders		North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders	Colitis	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0
Gastrointestinal disorders	Colitis	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Gastrointestinal disorders	Colitis	North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders		Asia Pacific and Australia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Australia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0
Immune system disorders		Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Immune system disorders		Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Immune system disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Immune system disorders	Hypersensitiviti y	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0
Immune system disorders	Hypersensitiviti y	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Immune system disorders	Hypersensitiviti y	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Infections and infestations		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Infections and infestations		North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations	Encephalitis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations	Encephalitis	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Infections and infestations	Encephalitis	North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations	Meningitis	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Infections and infestations	Meningitis	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Infections and infestations	Meningitis	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations		North America	10	9,6	1	10,0	10	9,9	0	0
Investigations	Alanine aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Alanine aminotransfera se increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Alanine aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Aspartate aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Aspartate aminotransfera se increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Aspartate aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Blood creatinine increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Blood creatinine increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Investigations	Blood creatinine increased	North America	10	9,6	1	10,0	10	9,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America	10	9,6	0	0,0	10	9,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders		Asia Pacific and Austral ia	29	27,9	3	10,3	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	North America	10	9,6	0	0,0	10	9,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Lung disorder	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	North America	10	9,6	0	0,0	10	9,9	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia Pacific and Austral ia	29	27,9	3	10,3	23	22,8	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 17:22

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: AEs leading to Atezolizumab Discontinuation
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Blood and lymphatic system disorders		IIB	27	26,0	1	3,7	15	14,9	0	0
Blood and lymphatic system disorders		IIIA	46	44,2	0	0,0	53	52,5	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIA	31	29,8	0	0,0	33	32,7	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIB	27	26,0	1	3,7	15	14,9	0	0
Blood and lymphatic system disorders	Sarcoidosis of lymph node	IIIA	46	44,2	0	0,0	53	52,5	0	0
Cardiac disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Cardiac disorders		IIB	27	26,0	0	0,0	15	14,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Cardiac disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Cardiac disorders	Atrial fibrillation	IIA	31	29,8	1	3,2	33	32,7	0	0
Cardiac disorders	Atrial fibrillation	IIB	27	26,0	0	0,0	15	14,9	0	0
Cardiac disorders	Atrial fibrillation	IIIA	46	44,2	0	0,0	53	52,5	0	0
Cardiac disorders	Cardiac failure	IIA	31	29,8	0	0,0	33	32,7	0	0
Cardiac disorders	Cardiac failure	IIB	27	26,0	0	0,0	15	14,9	0	0
Cardiac disorders	Cardiac failure	IIIA	46	44,2	1	2,2	53	52,5	0	0
Endocrine disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Endocrine disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Endocrine disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Endocrine disorders	Hypothyroidis m	IIA	31	29,8	1	3,2	33	32,7	0	0
Endocrine disorders	Hypothyroidis m	IIB	27	26,0	0	0,0	15	14,9	0	0
Endocrine disorders	Hypothyroidis m	IIIA	46	44,2	1	2,2	53	52,5	0	0
Gastrointesti nal disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Gastrointesti nal disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Gastrointesti nal disorders		IIIA	46	44,2	0	0,0	53	52,5	0	0
Gastrointesti nal disorders	Colitis	IIA	31	29,8	1	3,2	33	32,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Gastrointestinal disorders	Colitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Gastrointestinal disorders	Colitis	IIIA	46	44,2	0	0,0	53	52,5	0	0
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0
Immune system disorders		IIA	31	29,8	1	3,2	33	32,7	0	0
Immune system disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Immune system disorders		IIIA	46	44,2	0	0,0	53	52,5	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Immune system disorders	Hypersensitivity	IIA	31	29,8	1	3,2	33	32,7	0	0
Immune system disorders	Hypersensitivity	IIB	27	26,0	0	0,0	15	14,9	0	0
Immune system disorders	Hypersensitivity	IIIA	46	44,2	0	0,0	53	52,5	0	0
Infections and infestations		IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations		IIB	27	26,0	0	0,0	15	14,9	0	0
Infections and infestations		IIIA	46	44,2	2	4,3	53	52,5	0	0
Infections and infestations	Encephalitis	IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations	Encephalitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Infections and infestations	Encephalitis	IIIA	46	44,2	1	2,2	53	52,5	0	0
Infections and infestations	Meningitis	IIA	31	29,8	0	0,0	33	32,7	0	0
Infections and infestations	Meningitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Infections and infestations	Meningitis	IIIA	46	44,2	1	2,2	53	52,5	0	0
Investigations		IIA	31	29,8	0	0,0	33	32,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigation s		IIB	27	26,0	0	0,0	15	14,9	0	0
Investigation s		IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigation s	Alanine aminotransfer ase increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigation s	Alanine aminotransfer ase increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigation s	Alanine aminotransfer ase increased	IIIA	46	44,2	1	2,2	53	52,5	0	0
Investigation s	Aspartate aminotransfer ase increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigation s	Aspartate aminotransfer ase increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigation s	Aspartate aminotransfer ase increased	IIIA	46	44,2	1	2,2	53	52,5	0	0
Investigation s	Blood creatinine increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigation s	Blood creatinine increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigation s	Blood creatinine increased	IIIA	46	44,2	1	2,2	53	52,5	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIA	31	29,8	0	0,0	33	32,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIB	27	26,0	1	3,7	15	14,9	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		IIIA	46	44,2	0	0,0	53	52,5	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIA	31	29,8	0	0,0	33	32,7	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIB	27	26,0	1	3,7	15	14,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	IIIA	46	44,2	0	0,0	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders		IIA	31	29,8	3	9,7	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders		IIIA	46	44,2	2	4,3	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIA	31	29,8	0	0,0	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	IIIA	46	44,2	1	2,2	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIA	31	29,8	0	0,0	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIB	27	26,0	0	0,0	15	14,9	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Respiratory, thoracic and mediastinal disorders	Lung disorder	IIIA	46	44,2	1	2,2	53	52,5	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIA	31	29,8	3	9,7	33	32,7	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIB	27	26,0	0	0,0	15	14,9	0	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	IIIA	46	44,2	0	0,0	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

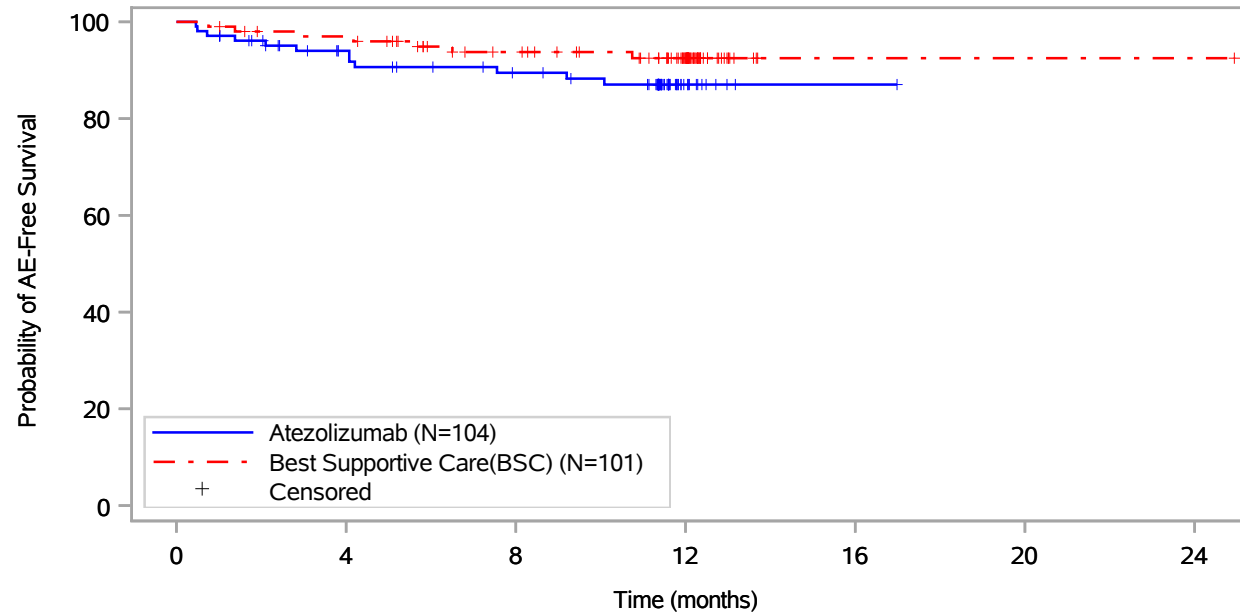
Generelle Verträglichkeit nach SOC/PT

KM Plots

Unstratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Blood and lymphatic system disorders, All



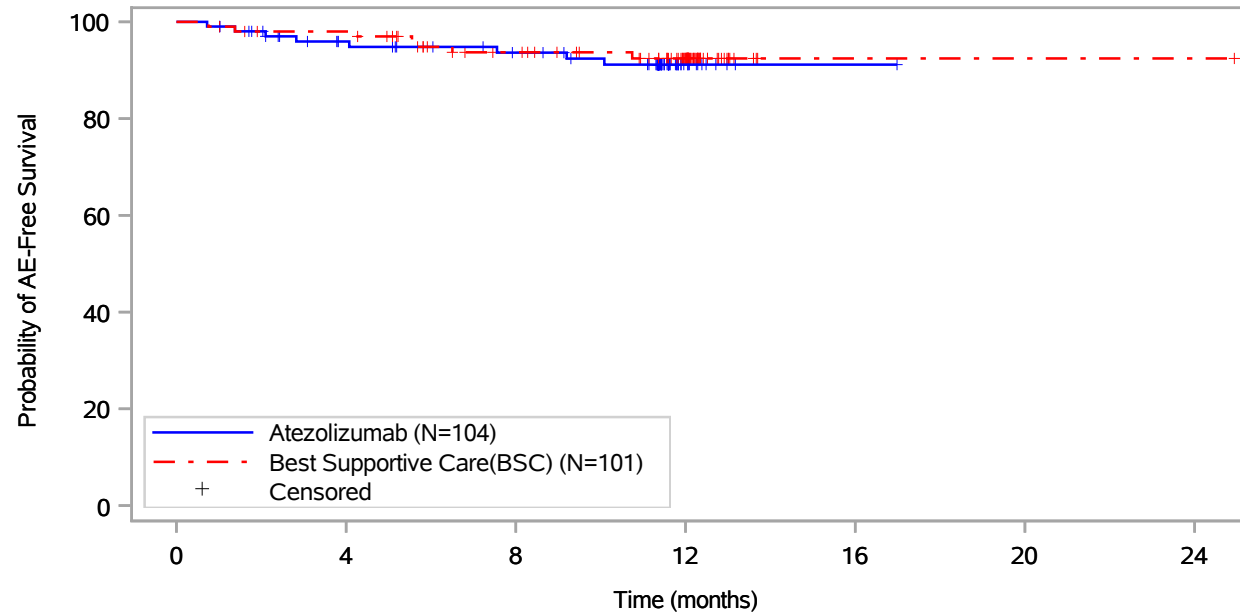
Patients at risk							
Atezolizumab (N=104)	104	84	75	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	80	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	80	91	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	41	93	93	93

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Blood and lymphatic system disorders, Anaemia



Patients at risk							
Atezolizumab (N=104)	104	86	78	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	80	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	84	95	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	41	93	93	93

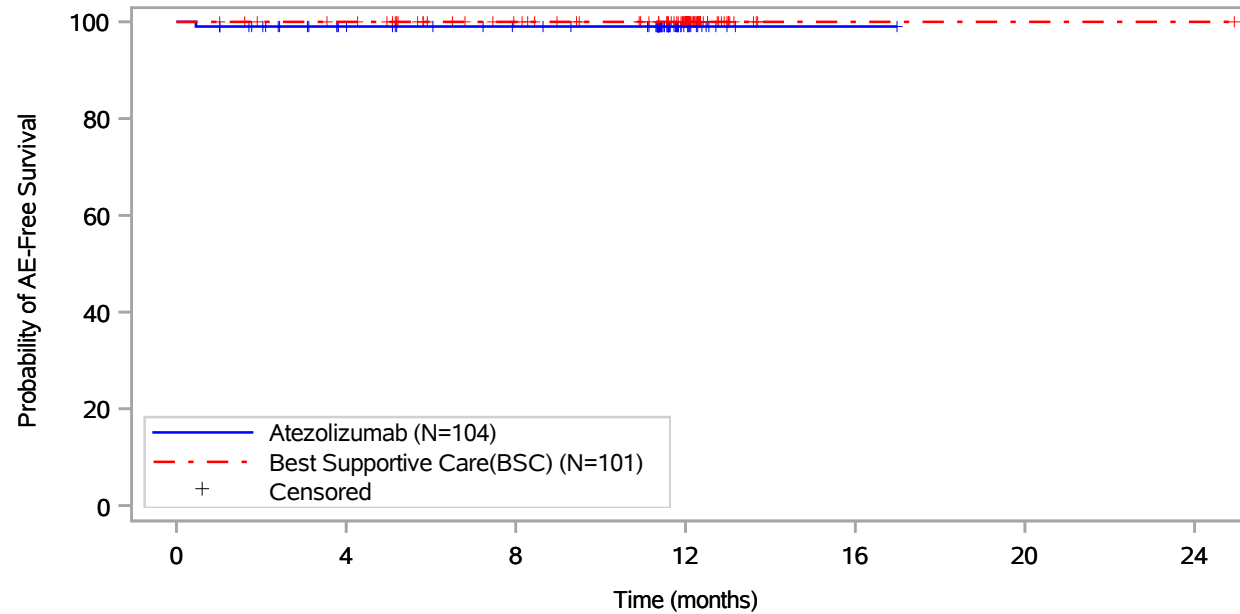
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

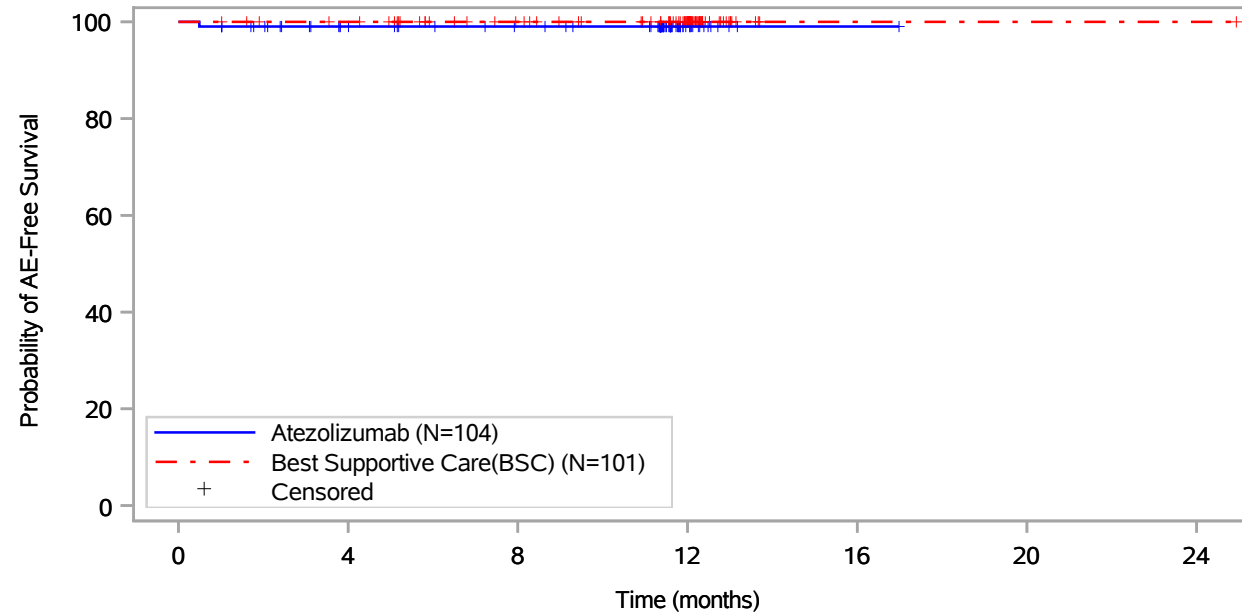
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Lymphadenopathy



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

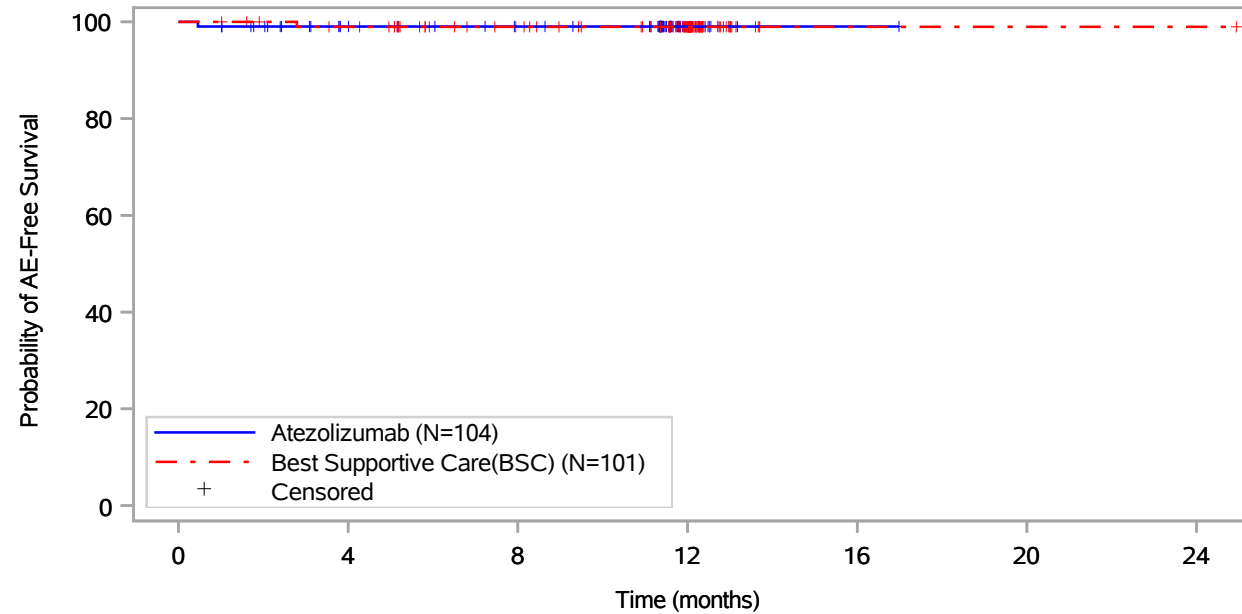
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

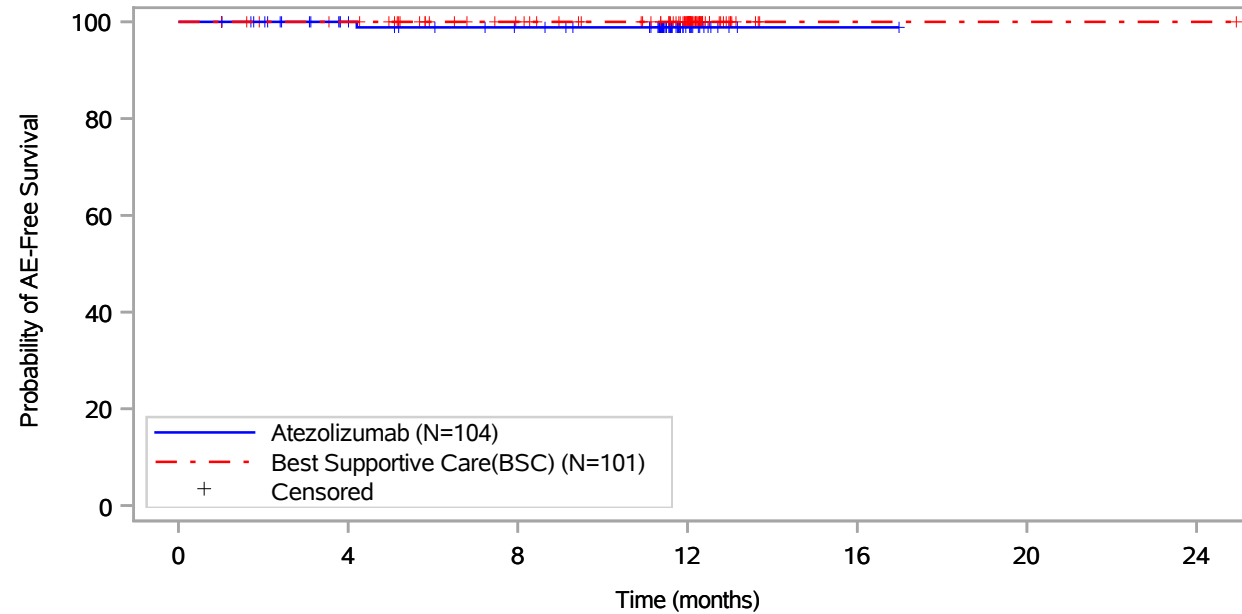
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Sarcoidosis of lymph node



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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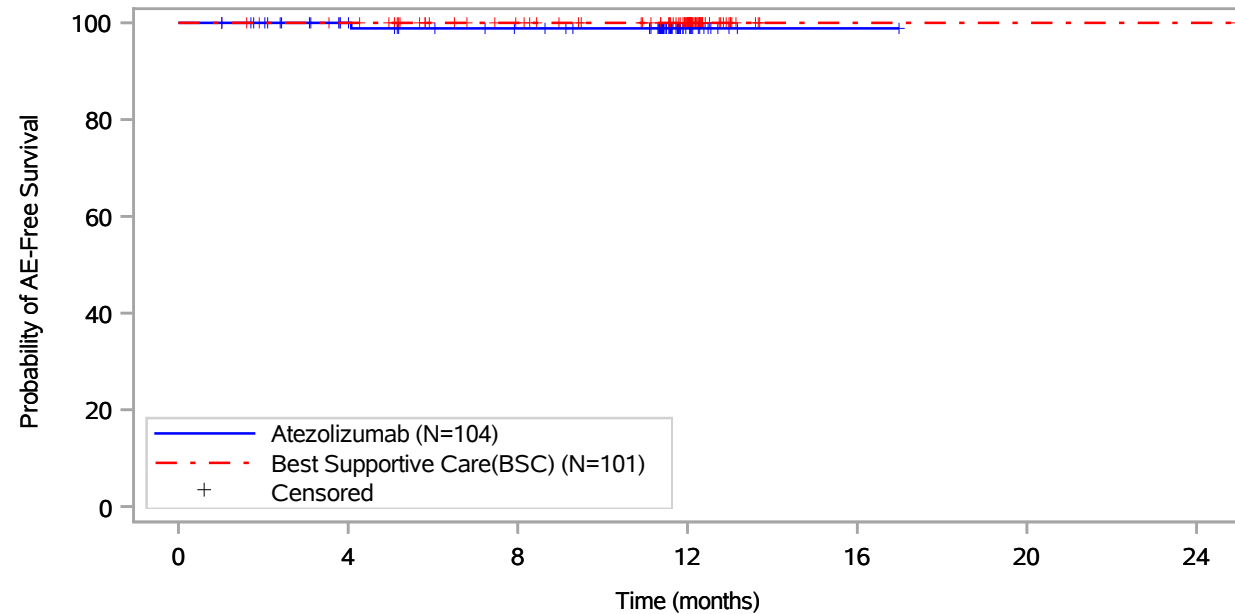
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



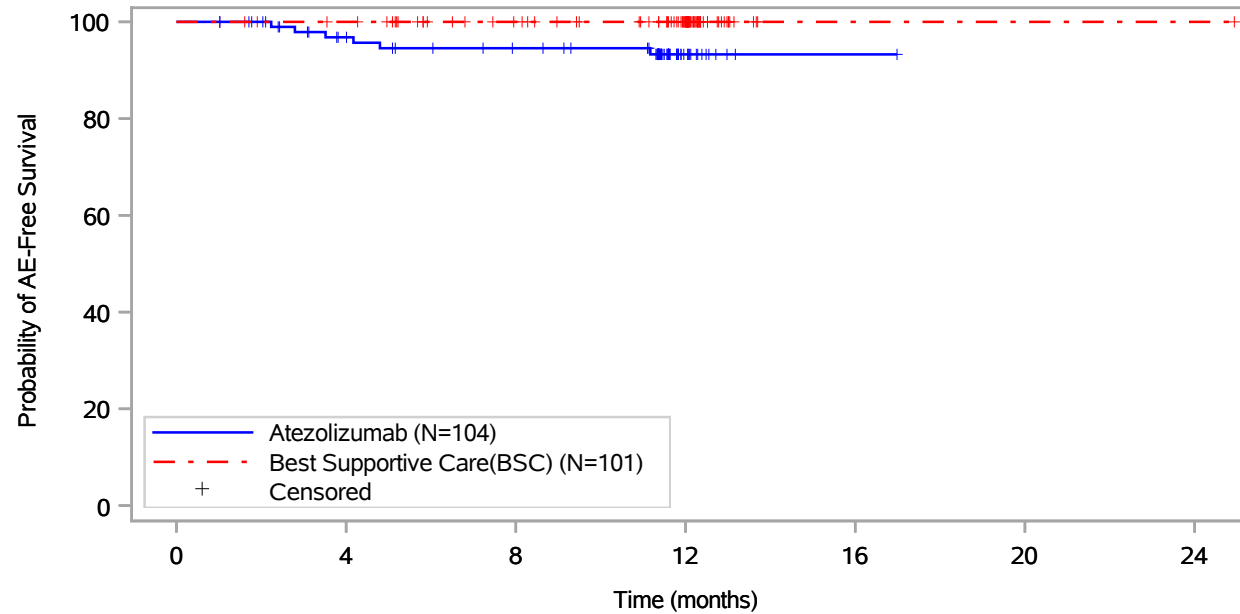
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, All



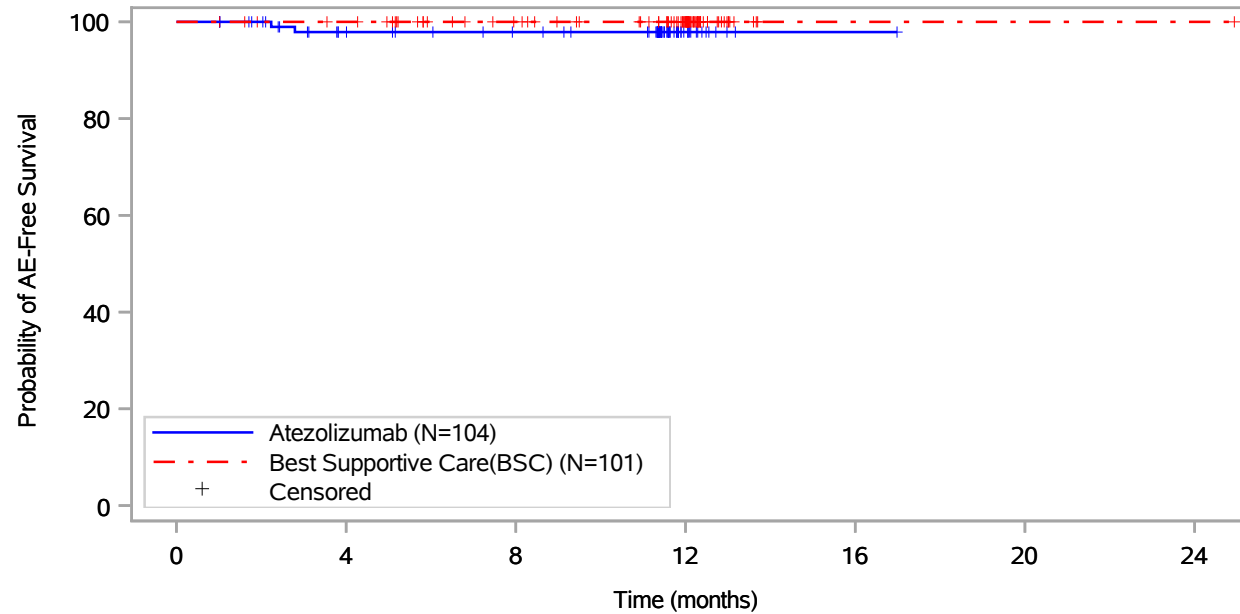
Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	84	97	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Atrial fibrillation



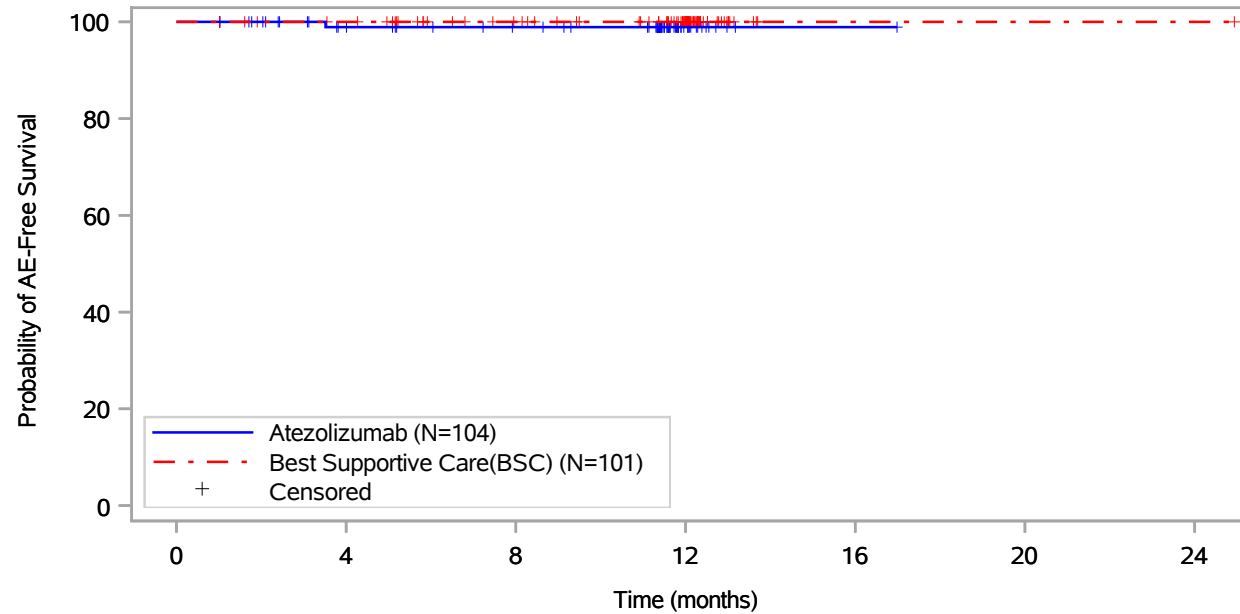
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	88	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Cardiac failure



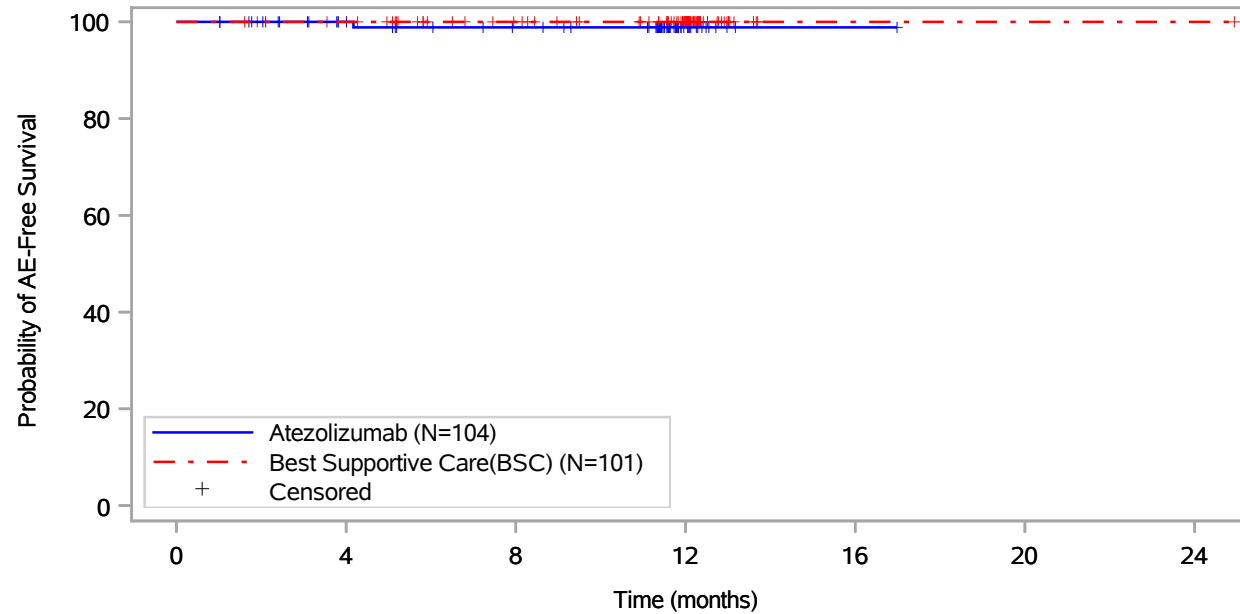
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Cardiac failure chronic



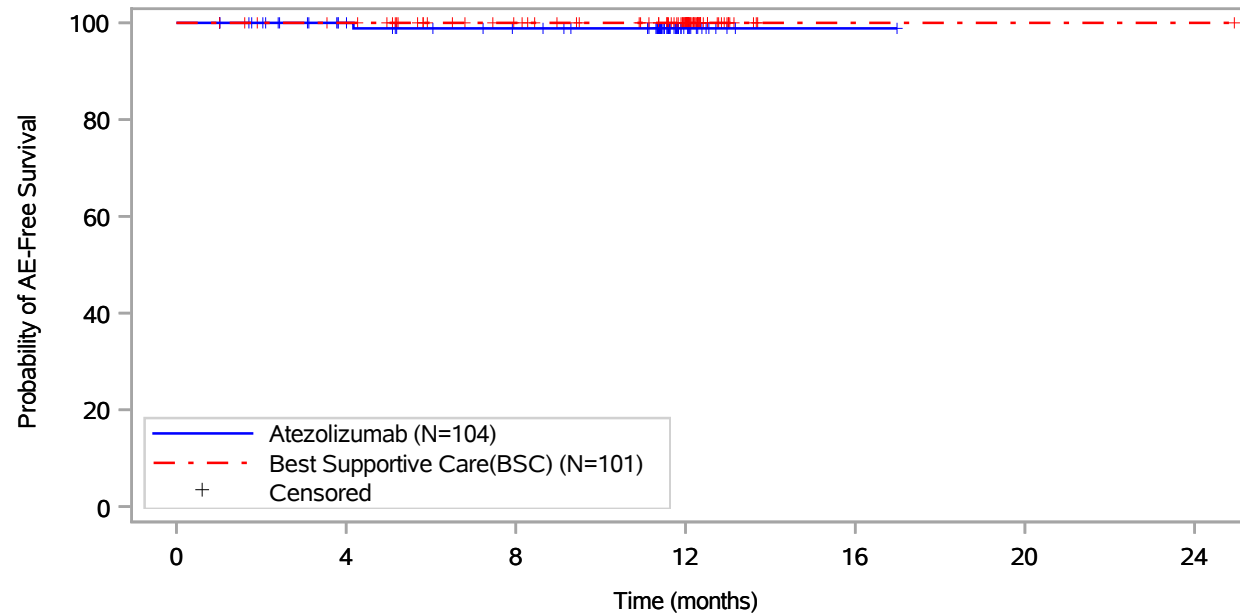
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Metabolic cardiomyopathy



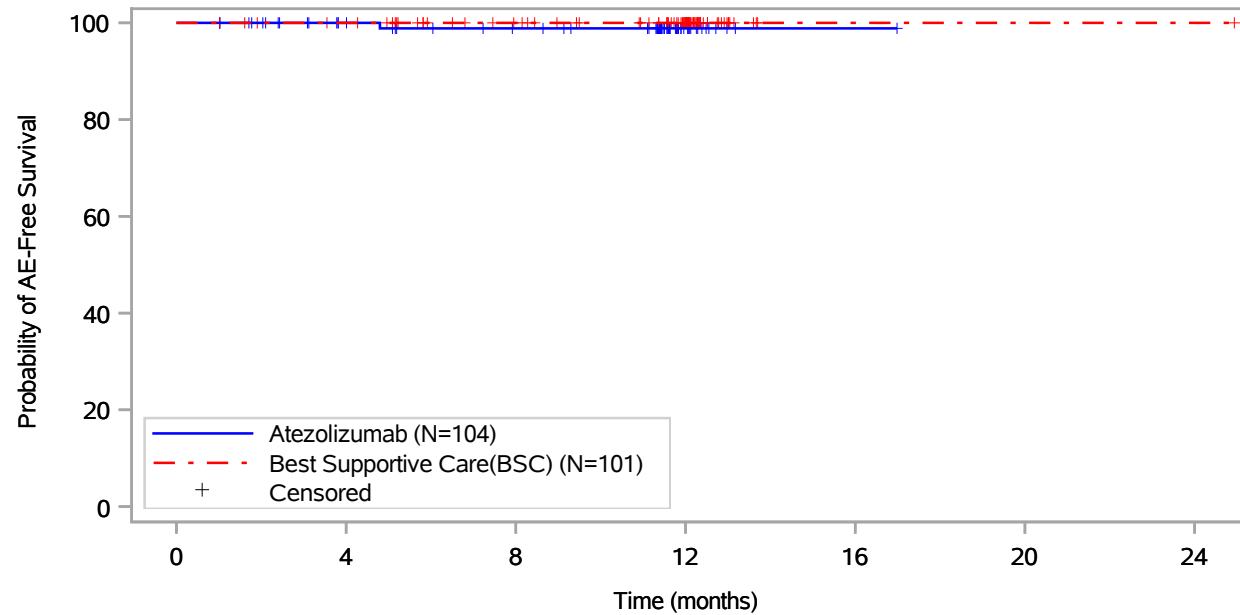
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Palpitations



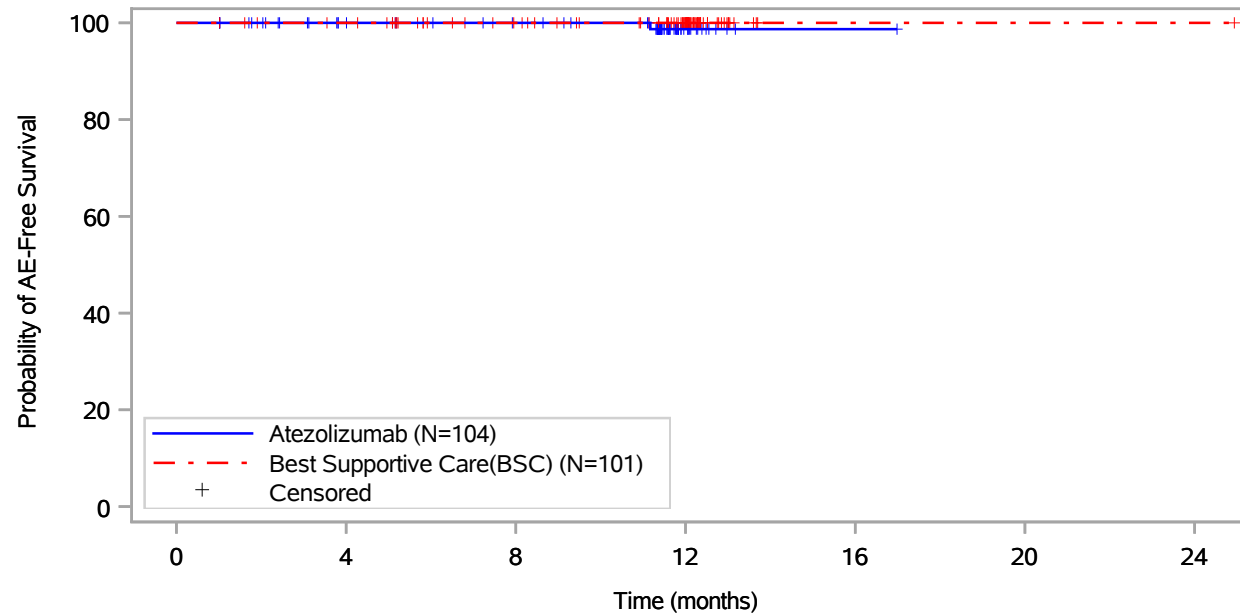
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Cardiac disorders, Sinus bradycardia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

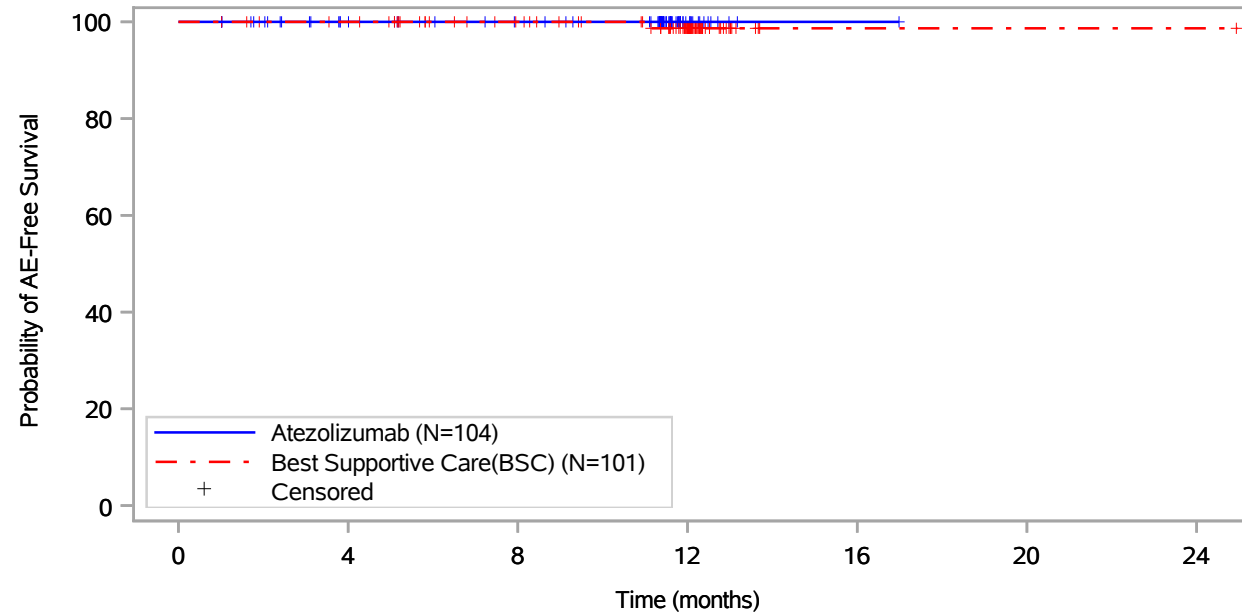
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Congenital, familial and genetic disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

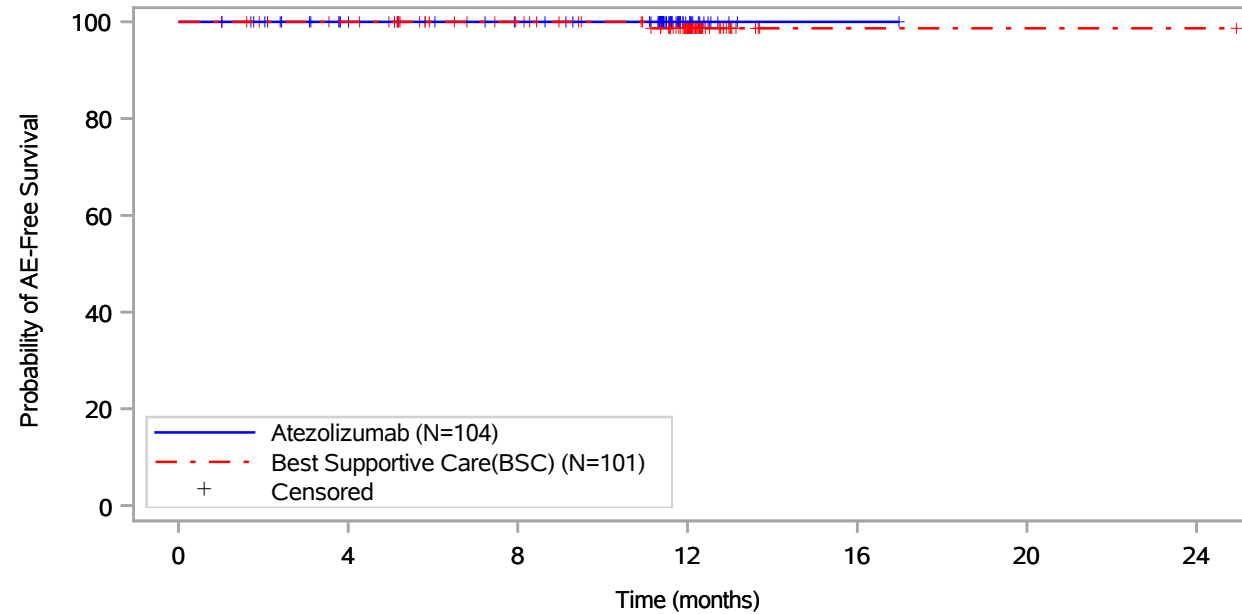
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Congenital, familial and genetic disorders, Gilbert's syndrome



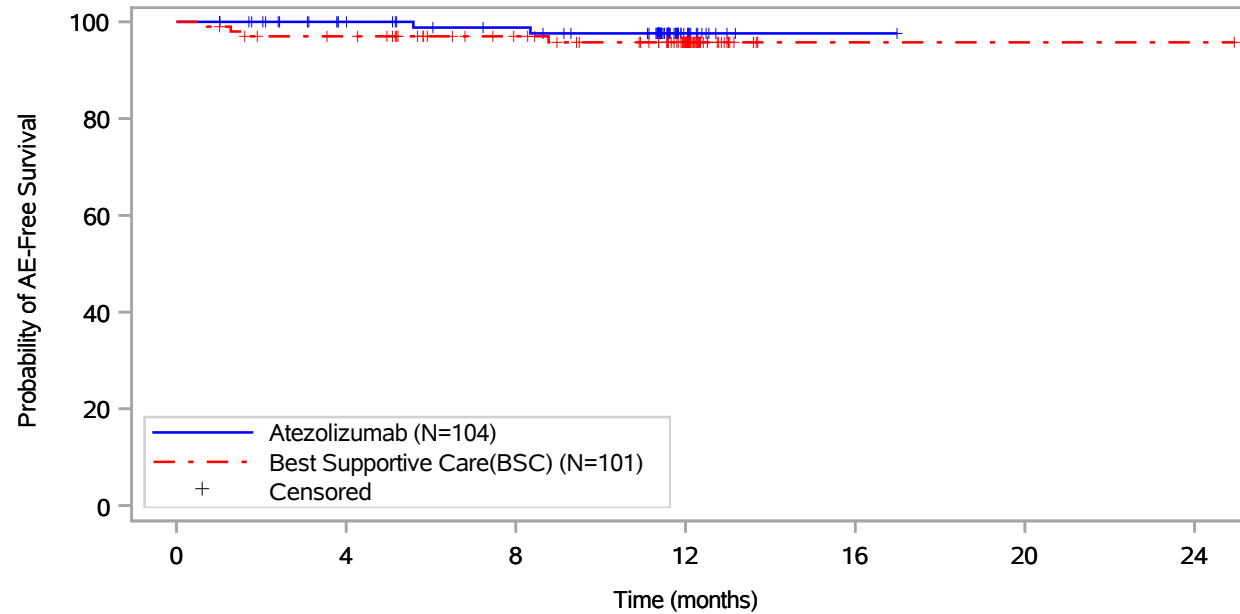
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Ear and labyrinth disorders, All



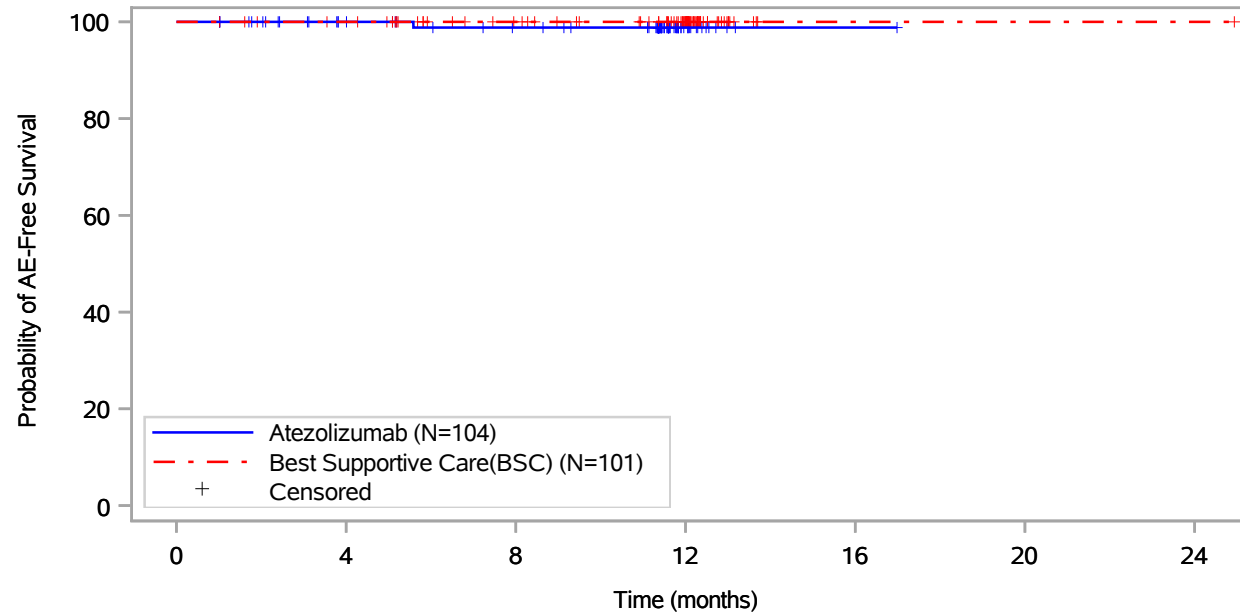
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	80	52	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	96	96	96

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Ear and labyrinth disorders, Ear discomfort



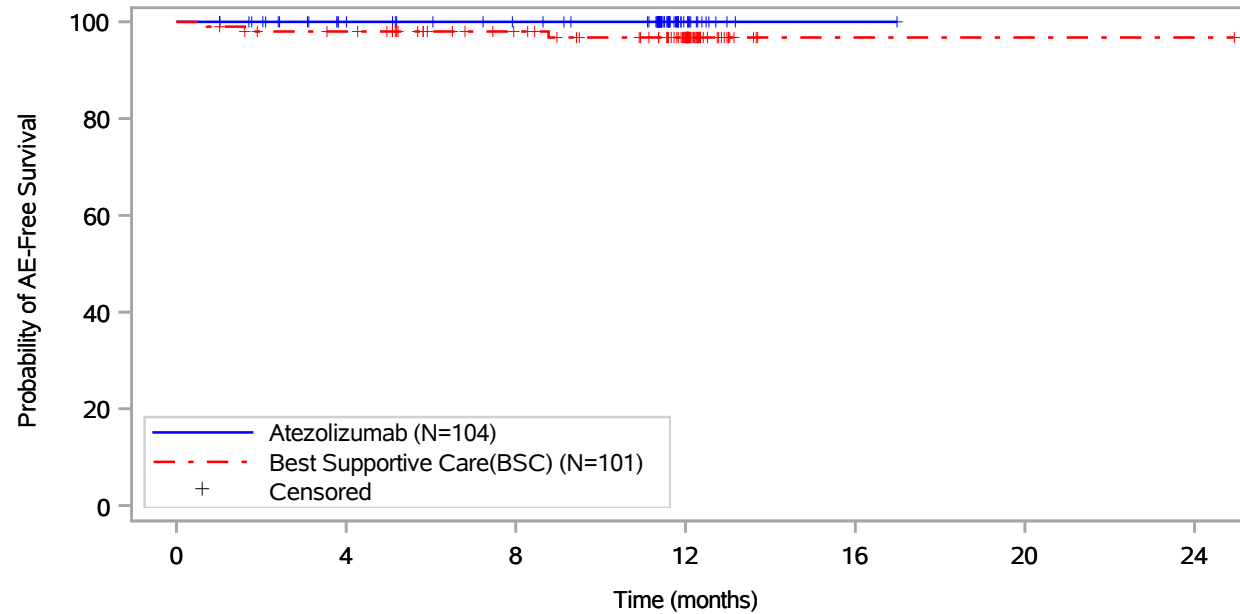
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Ear and labyrinth disorders, Tinnitus



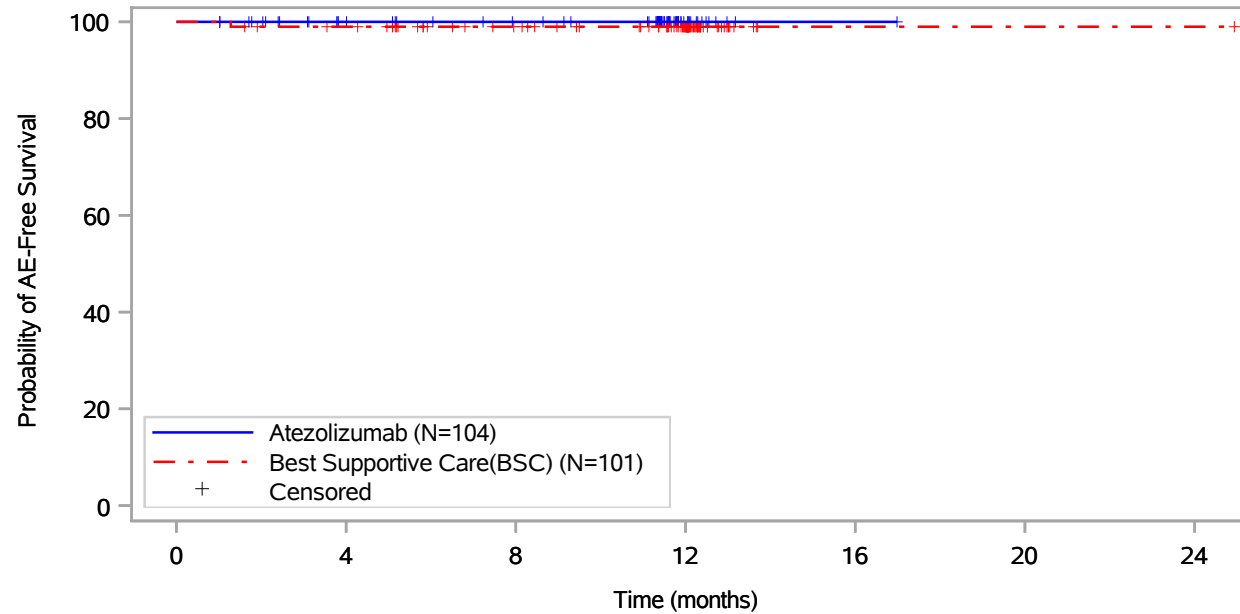
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	53	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	97	97	97	97

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Ear and labyrinth disorders, Vertigo



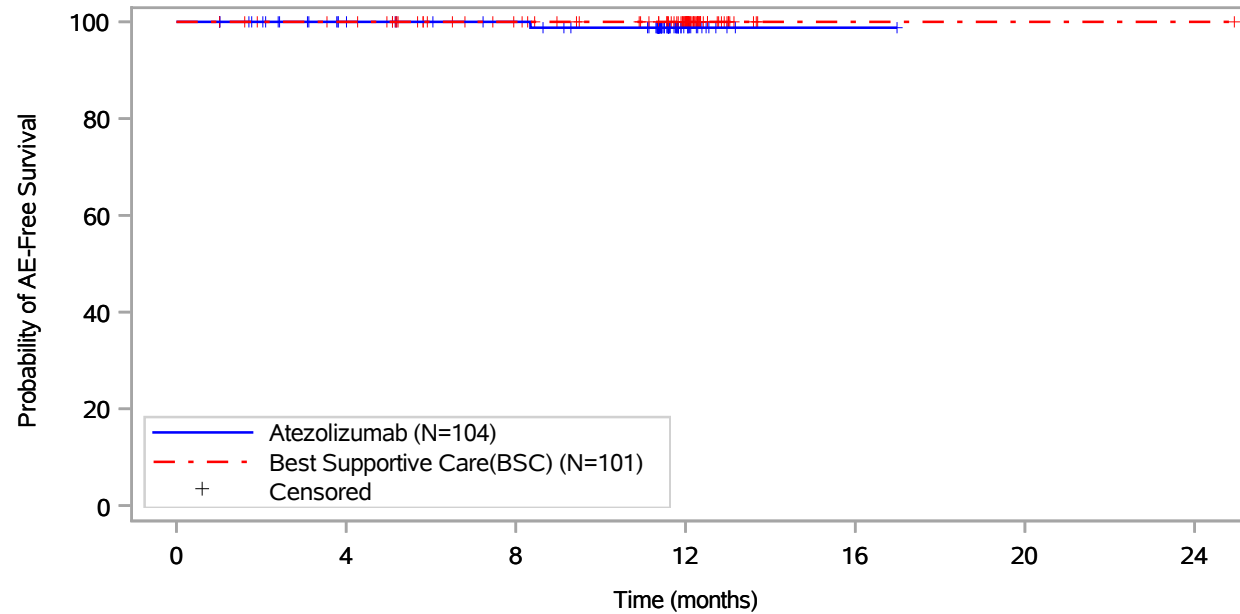
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Ear and labyrinth disorders, Vestibular ataxia



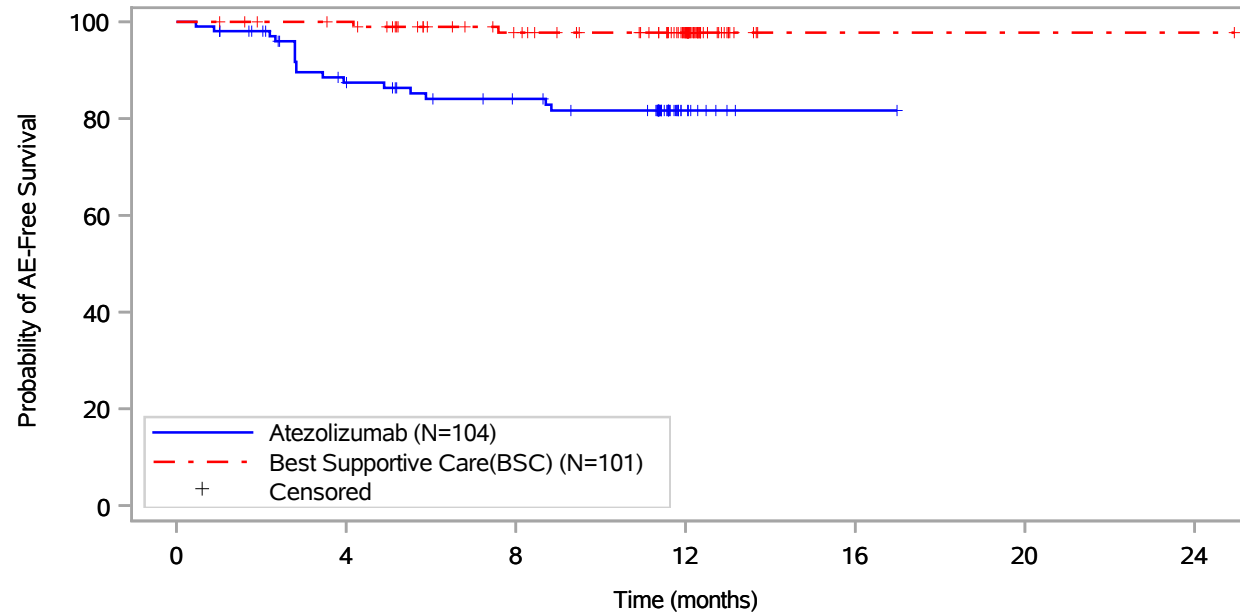
Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Endocrine disorders, All



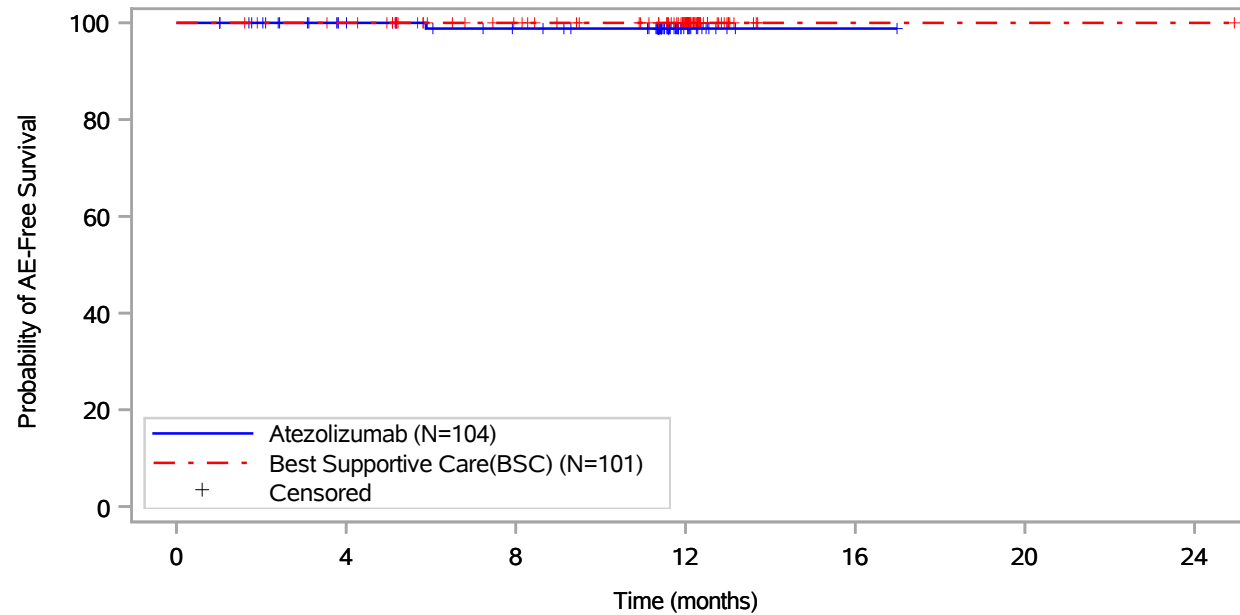
Patients at risk							
Atezolizumab (N=104)	104	81	71	10	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	11	18	77	86	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Endocrine disorders, Autoimmune thyroiditis



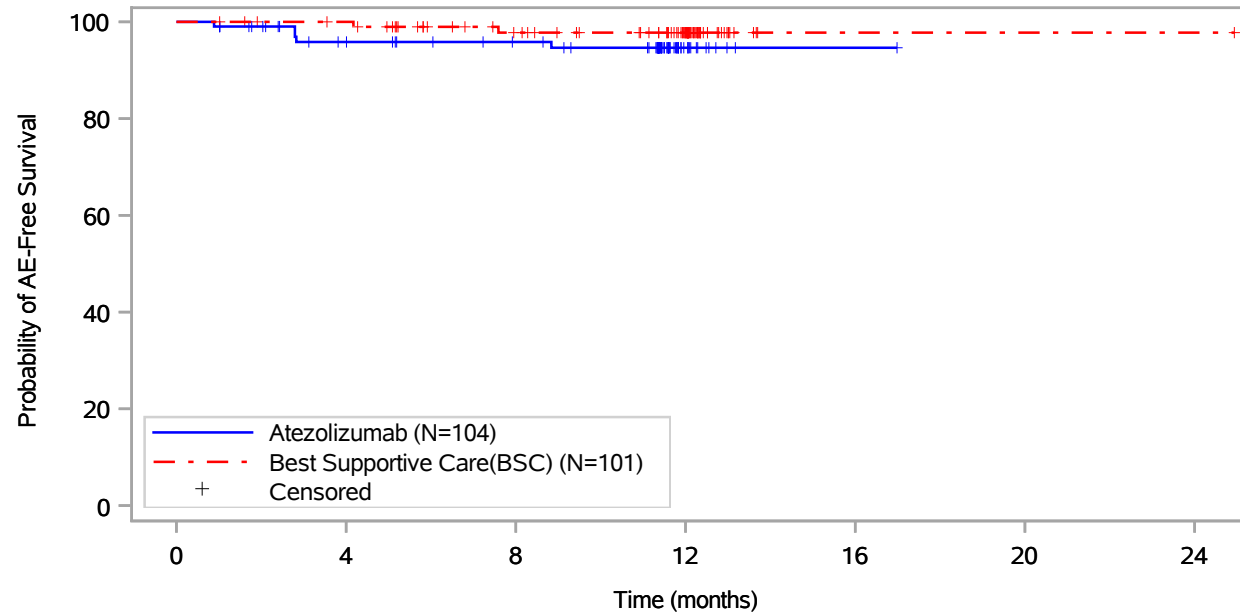
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Endocrine disorders, Hyperthyroidism



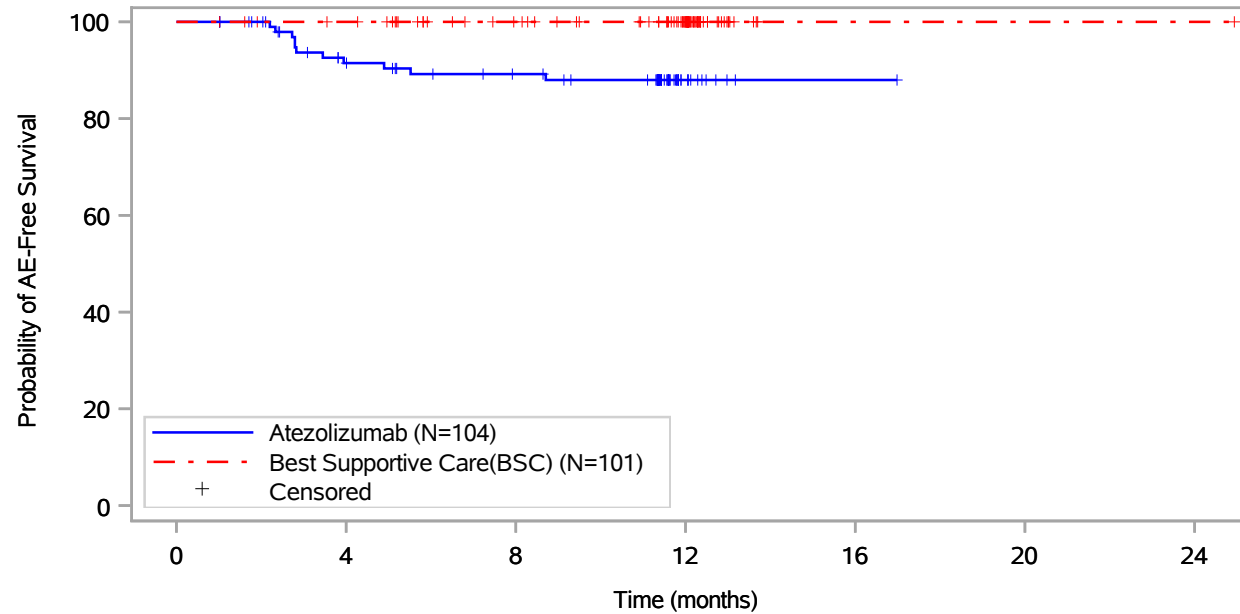
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	12	19	86	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Endocrine disorders, Hypothyroidism



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	83	74	11	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	13	20	82	92	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

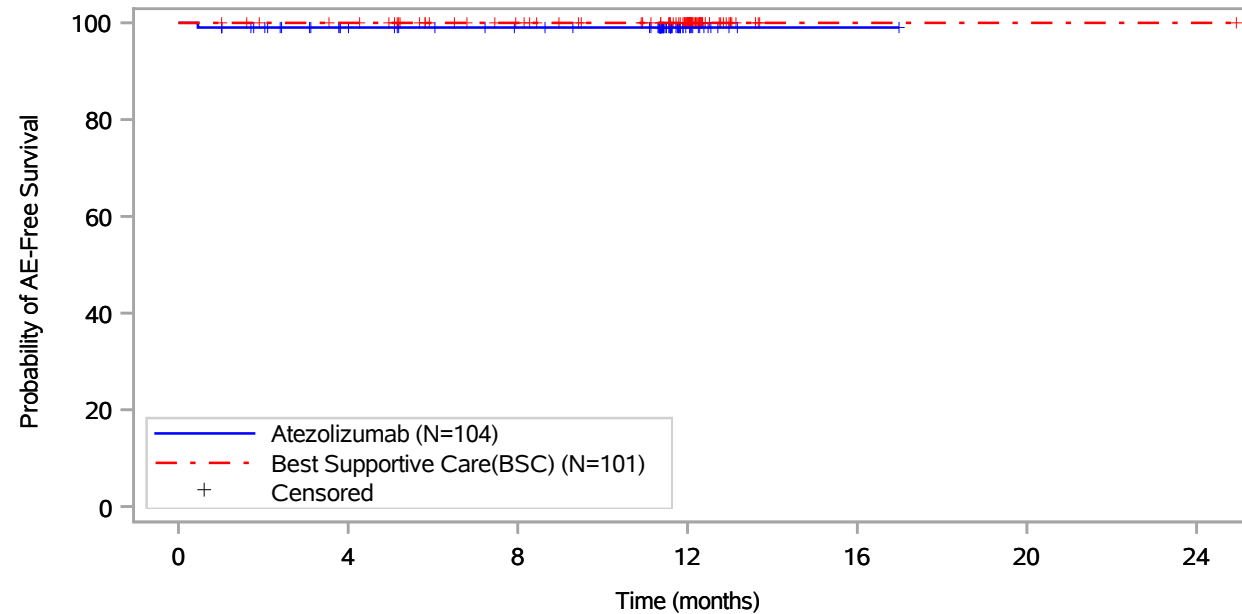
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



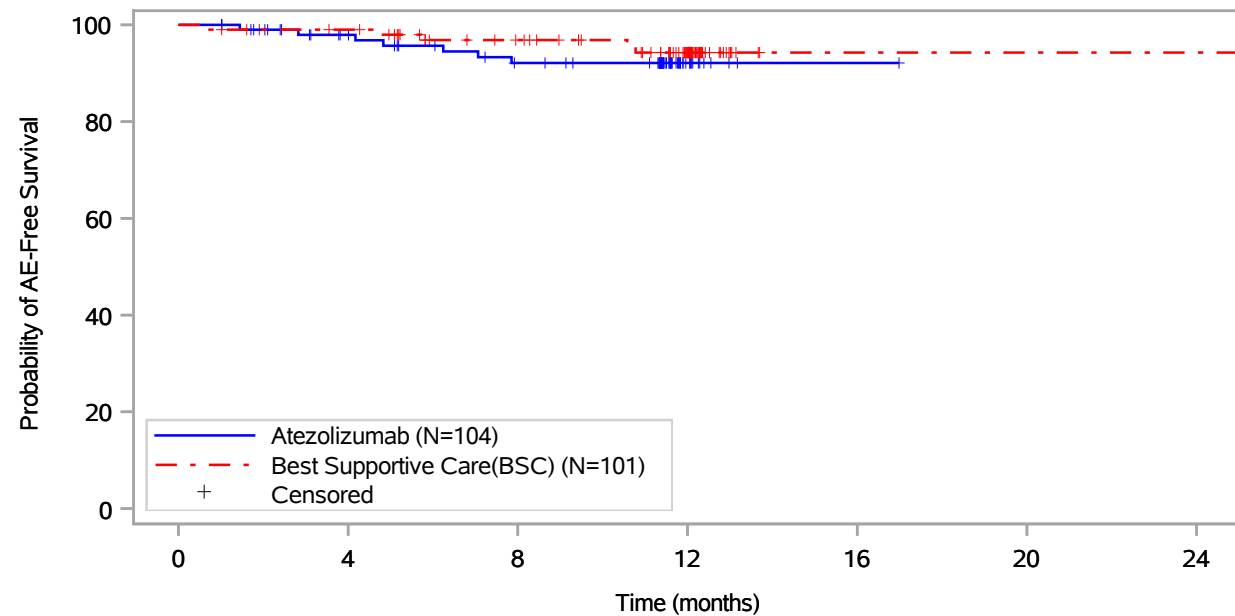
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, All



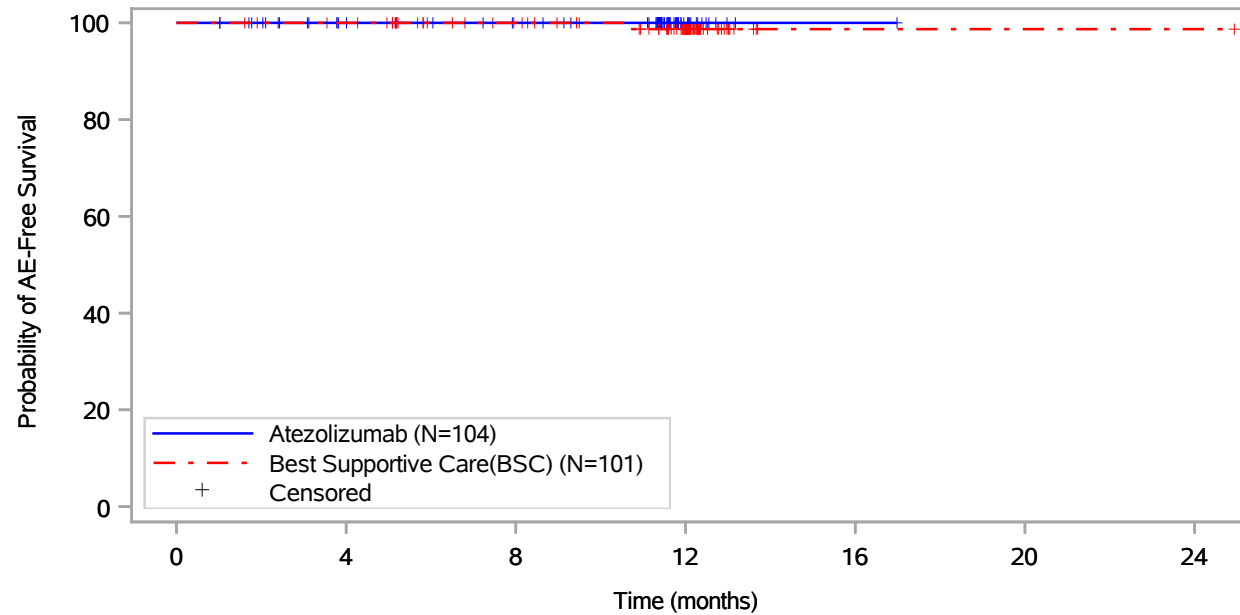
Patients at risk							
Atezolizumab (N=104)	104	88	76	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	52	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	85	96	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Blepharitis



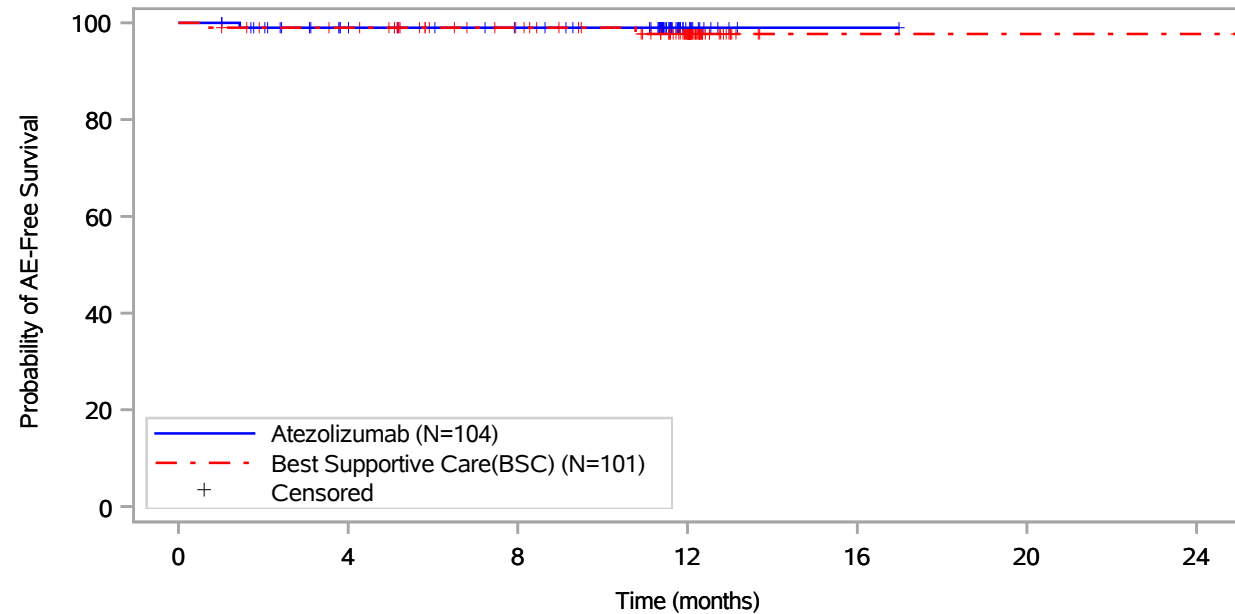
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Cataract



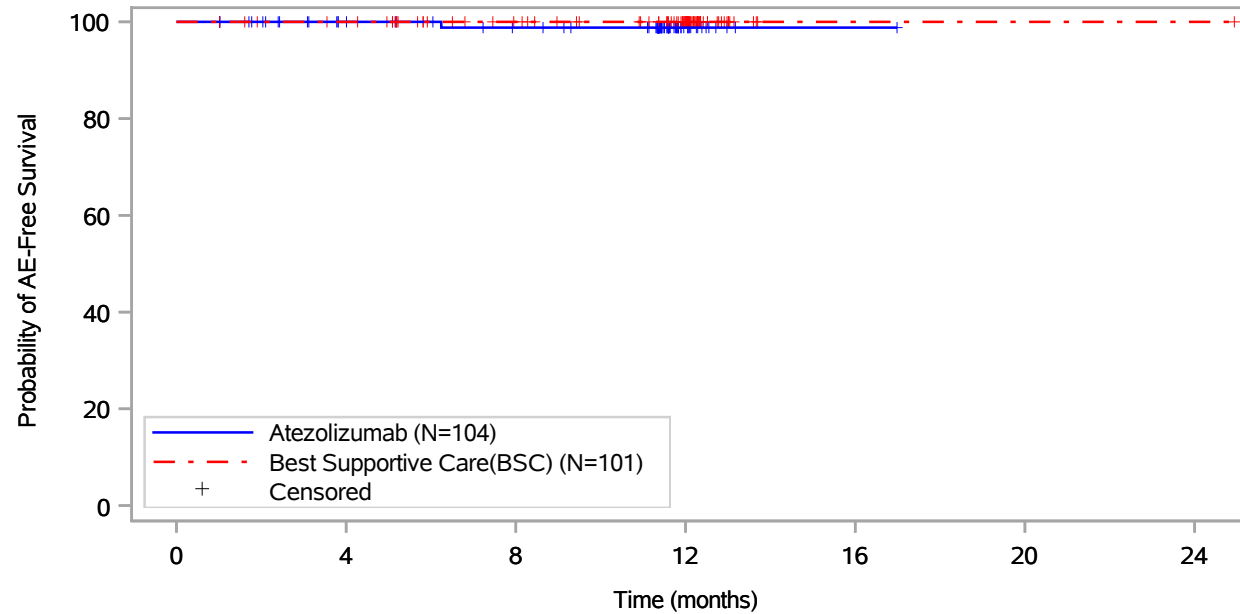
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Dry eye



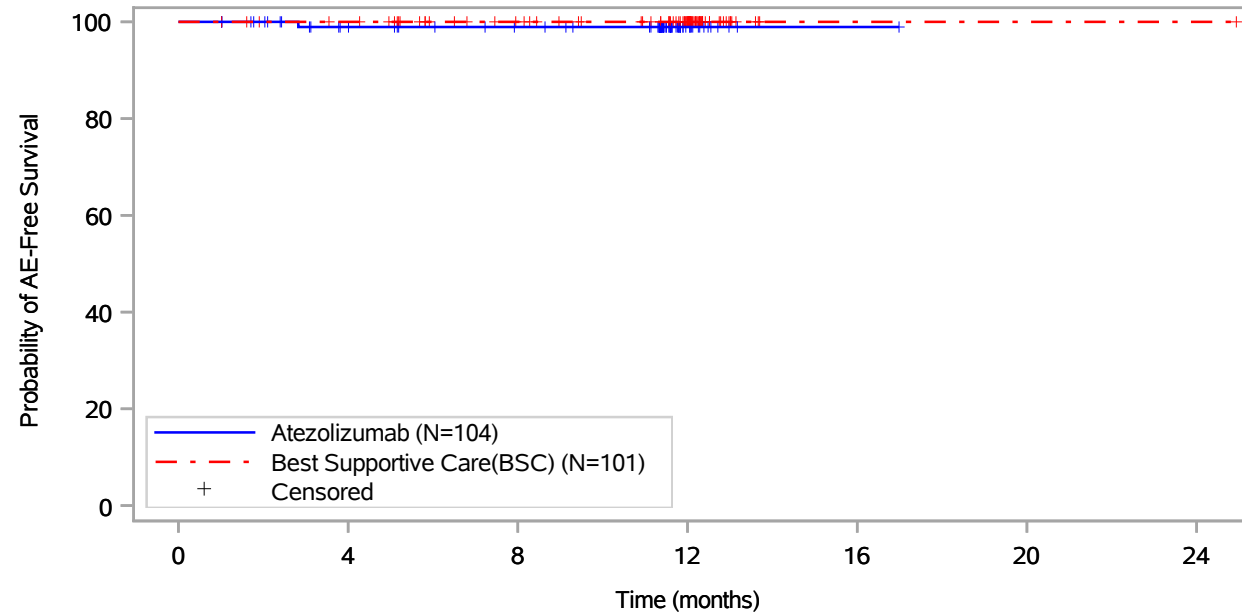
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Eyelid oedema



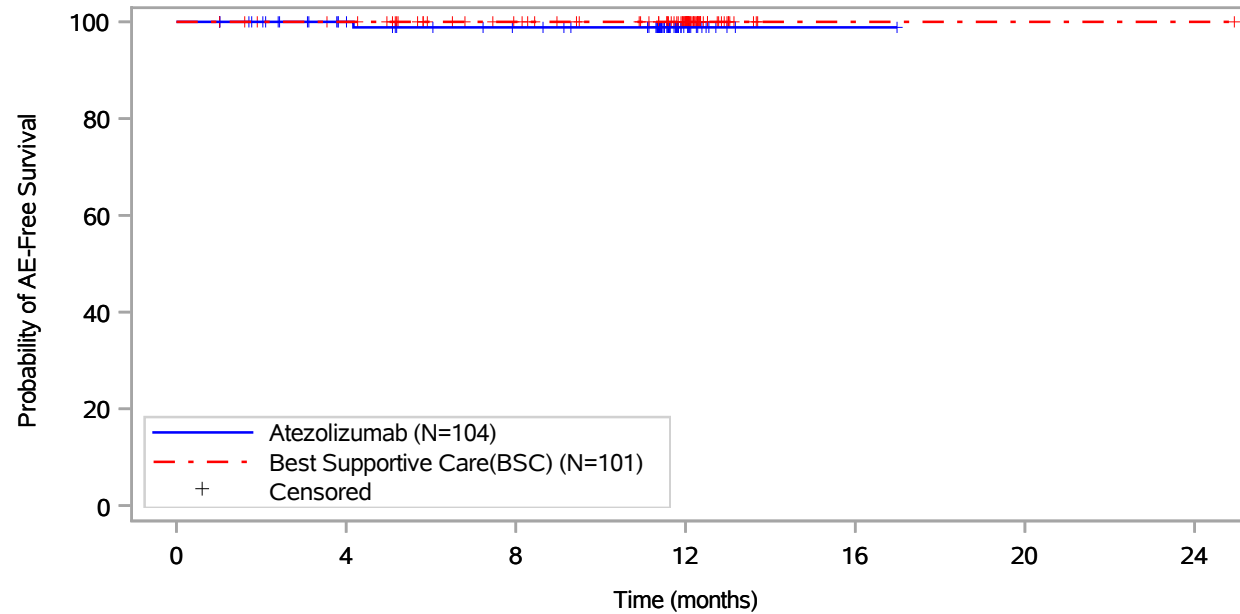
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Ocular discomfort



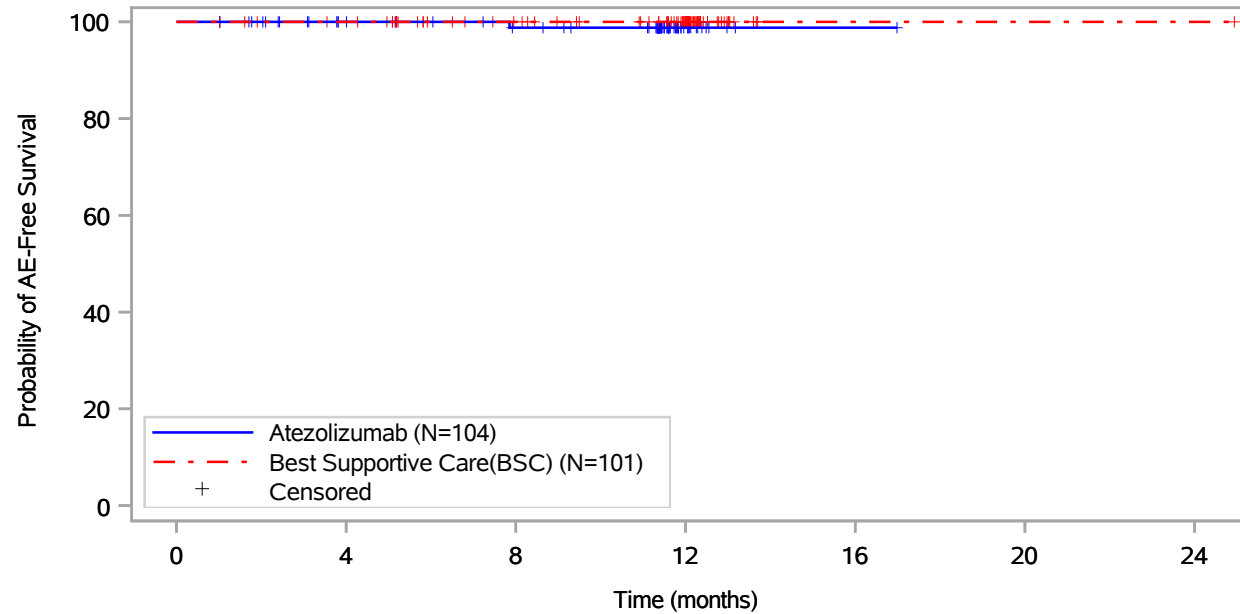
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Retinal detachment



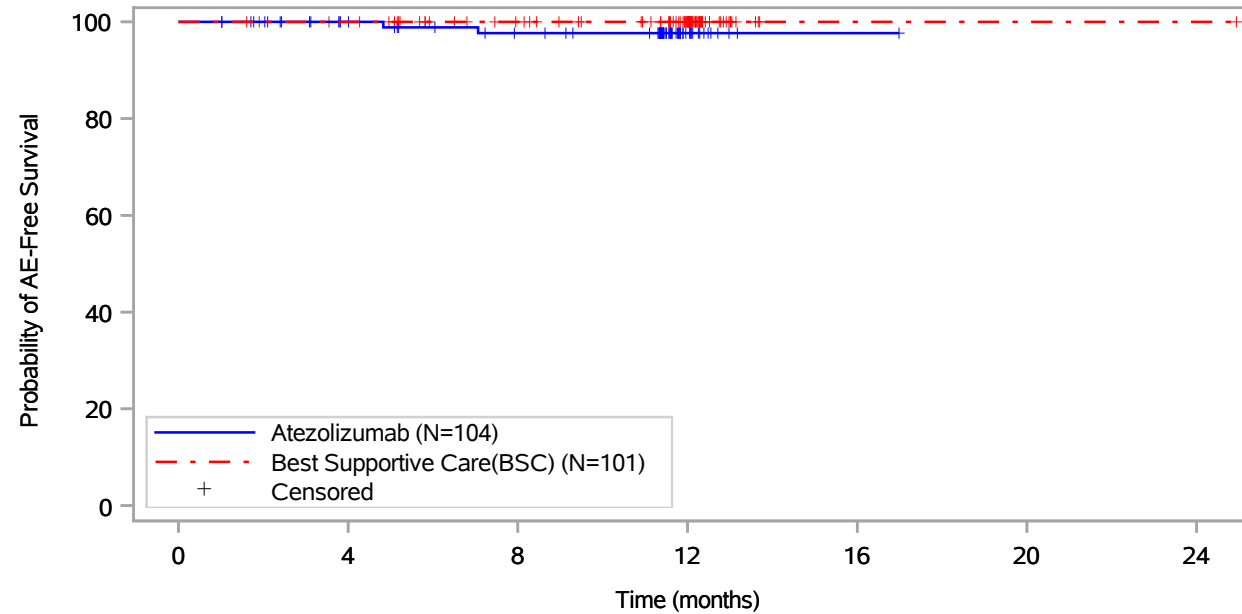
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Vision blurred



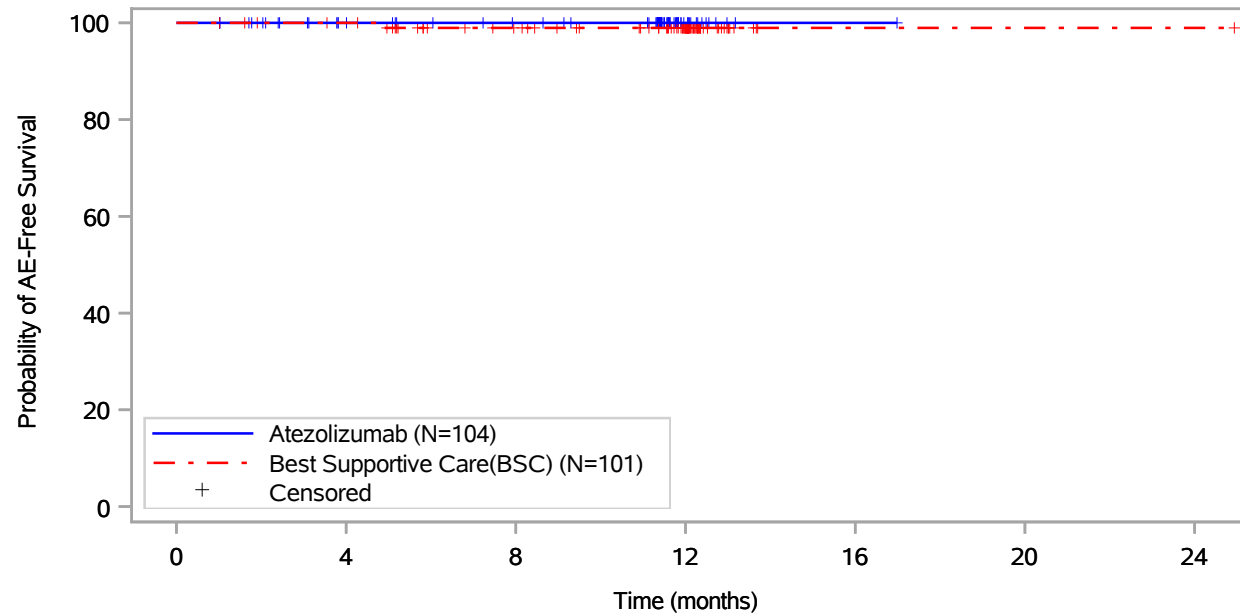
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	80	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	88	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Visual impairment



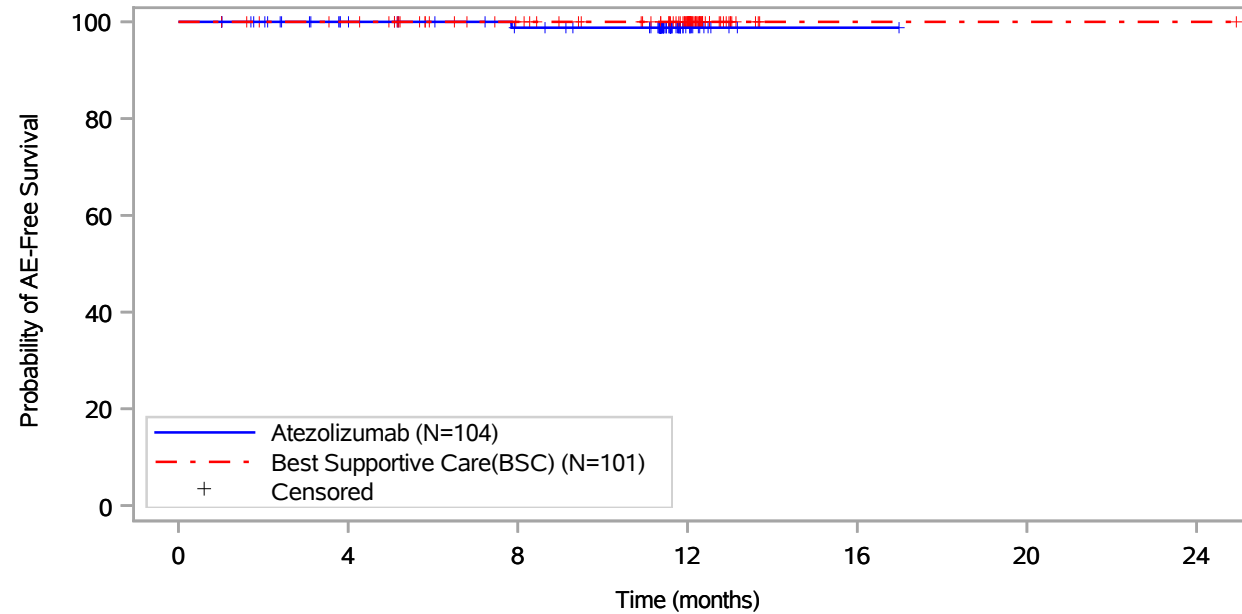
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Vitreous floaters



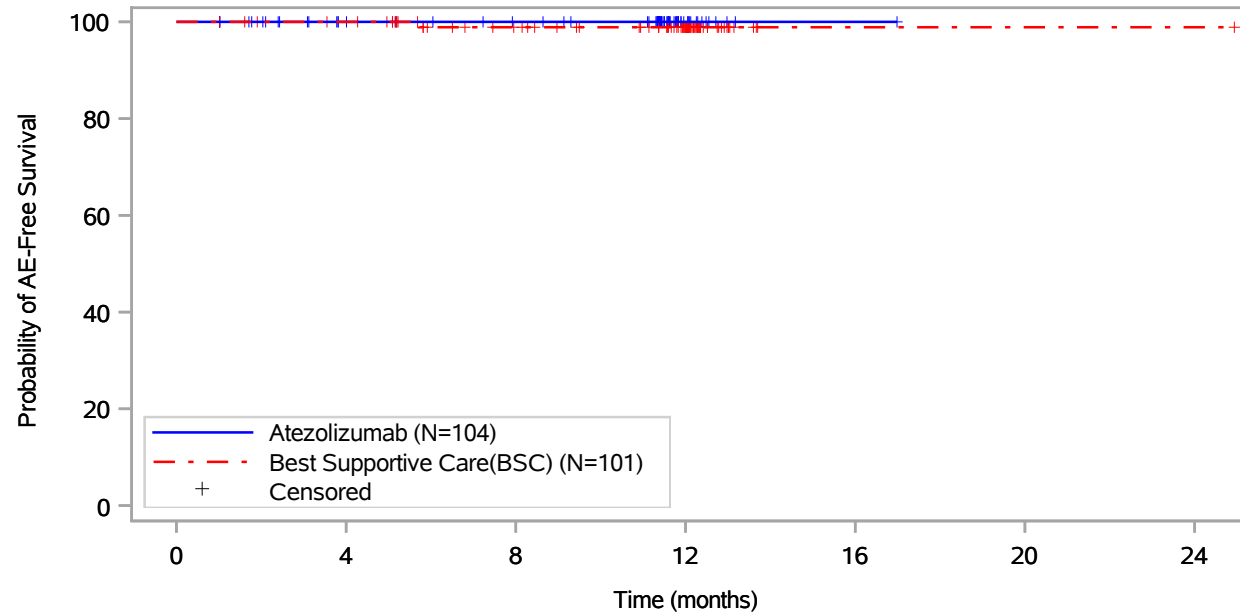
Patients at risk							
Atezolizumab (N=104)	104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Eye disorders, Vitreous haemorrhage



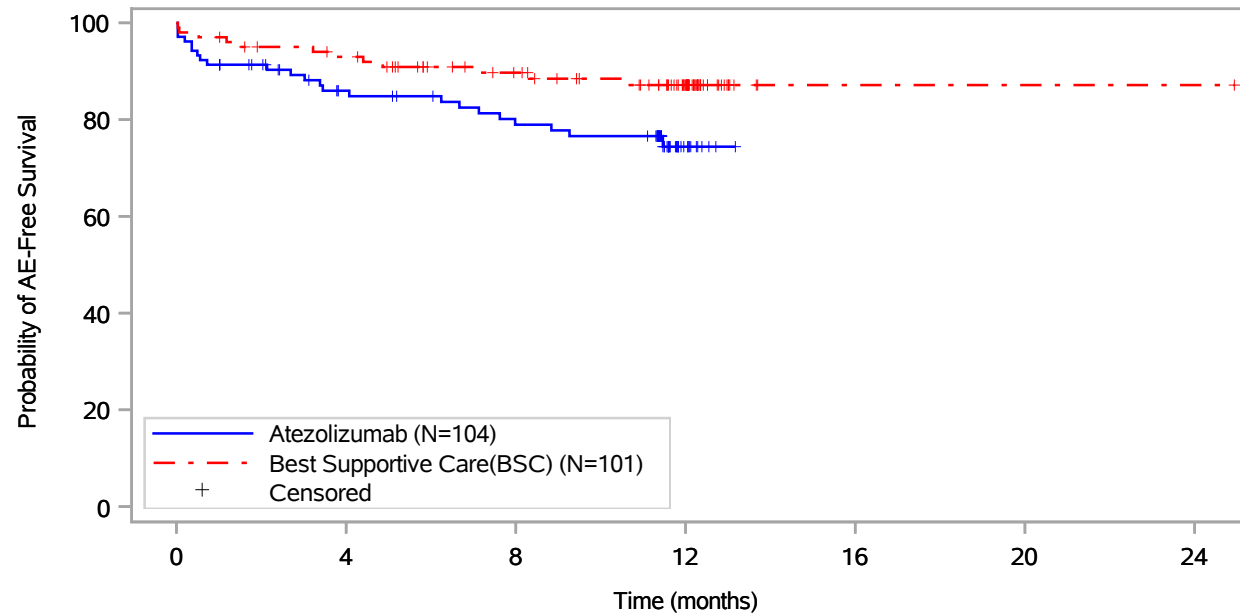
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	76	67	11	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	90	74	47	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	17	70	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	42	88	88	88

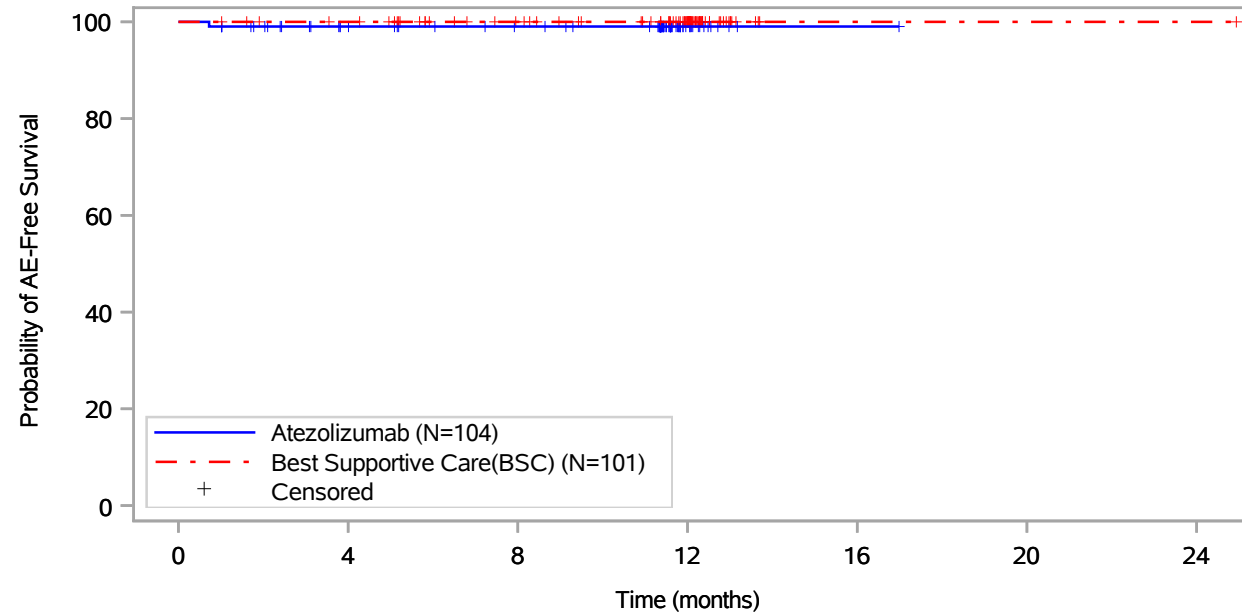
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Gastrointestinal disorders, Abdominal distension



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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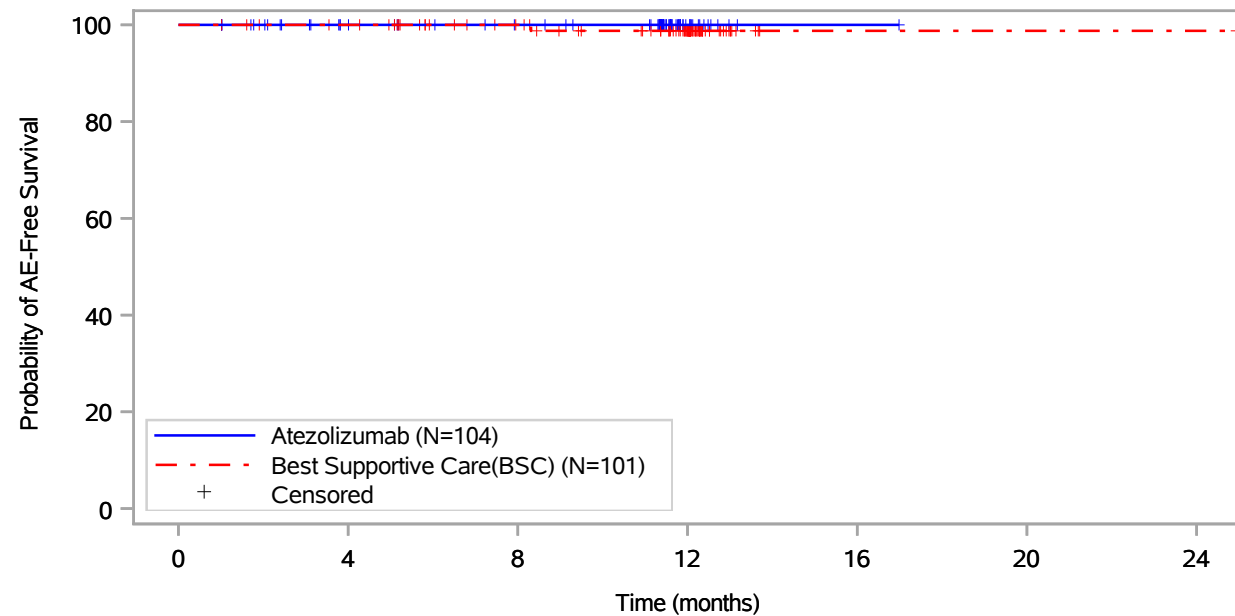
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal hernia



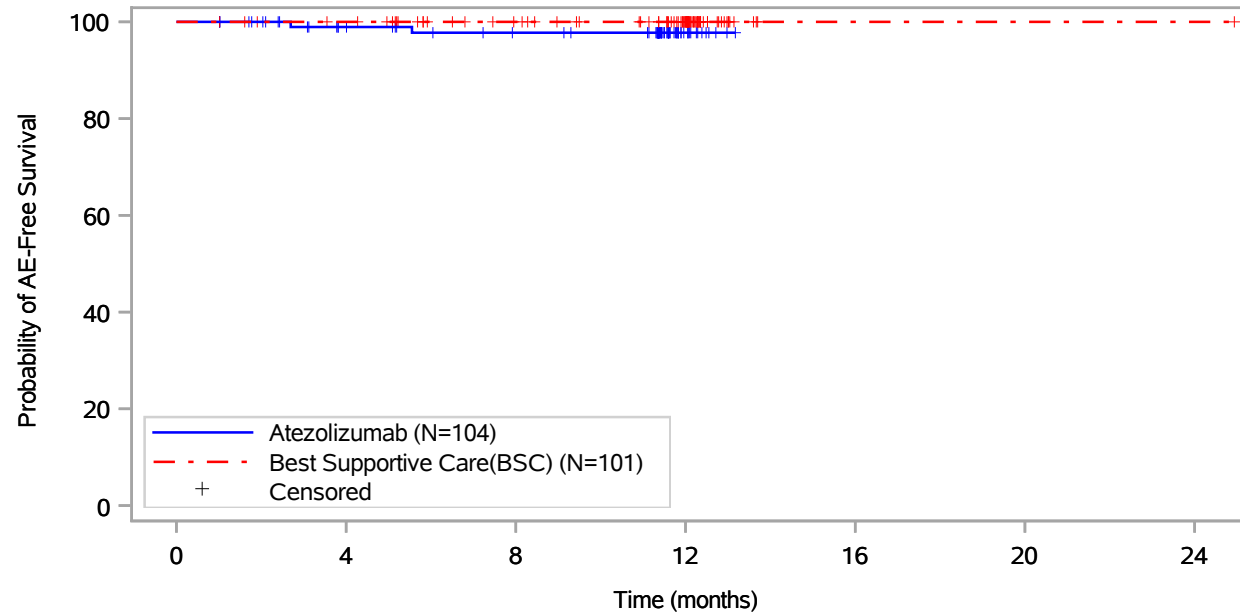
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Abdominal pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	80	13	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

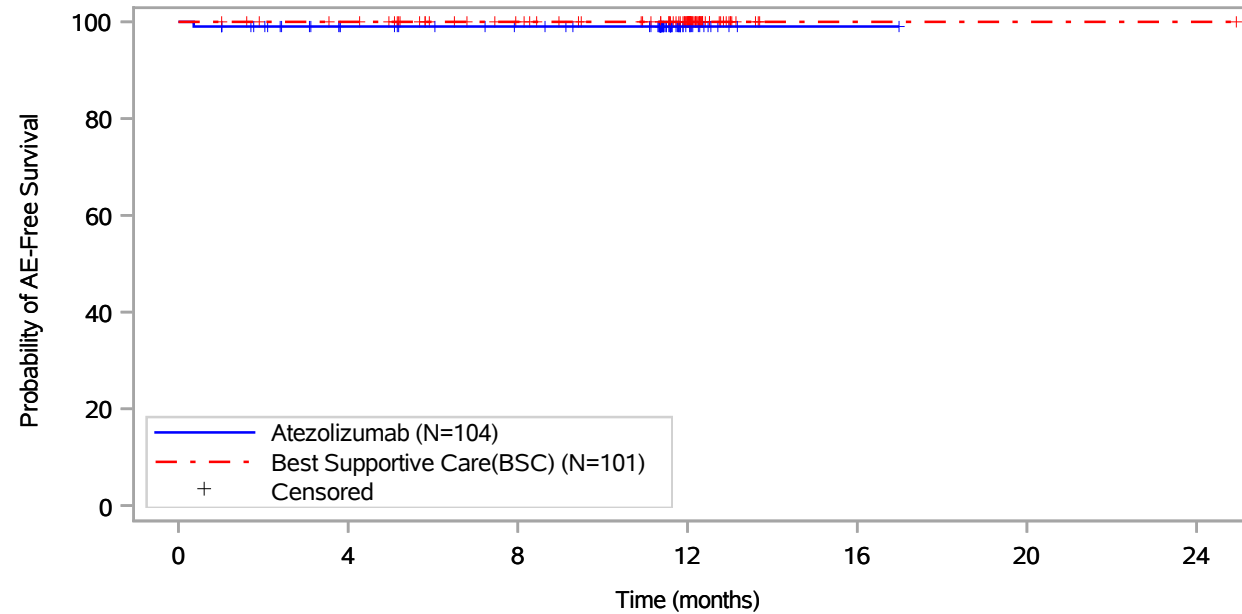
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Gastrointestinal disorders, Abdominal pain lower



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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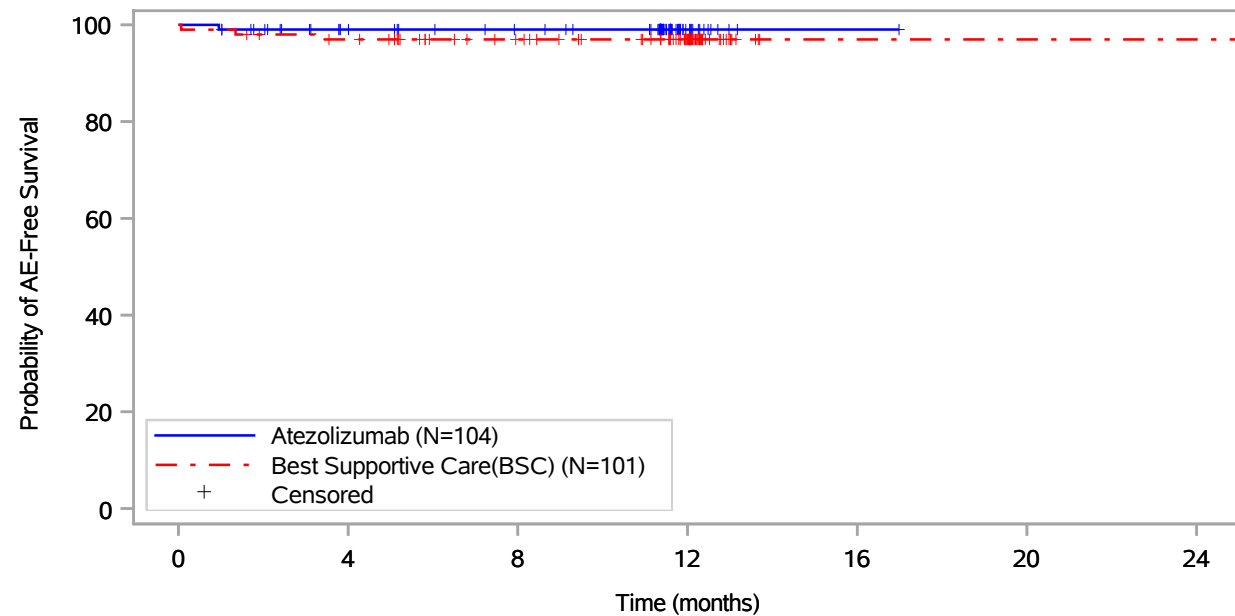
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Abdominal pain upper



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	80	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	97	97	97

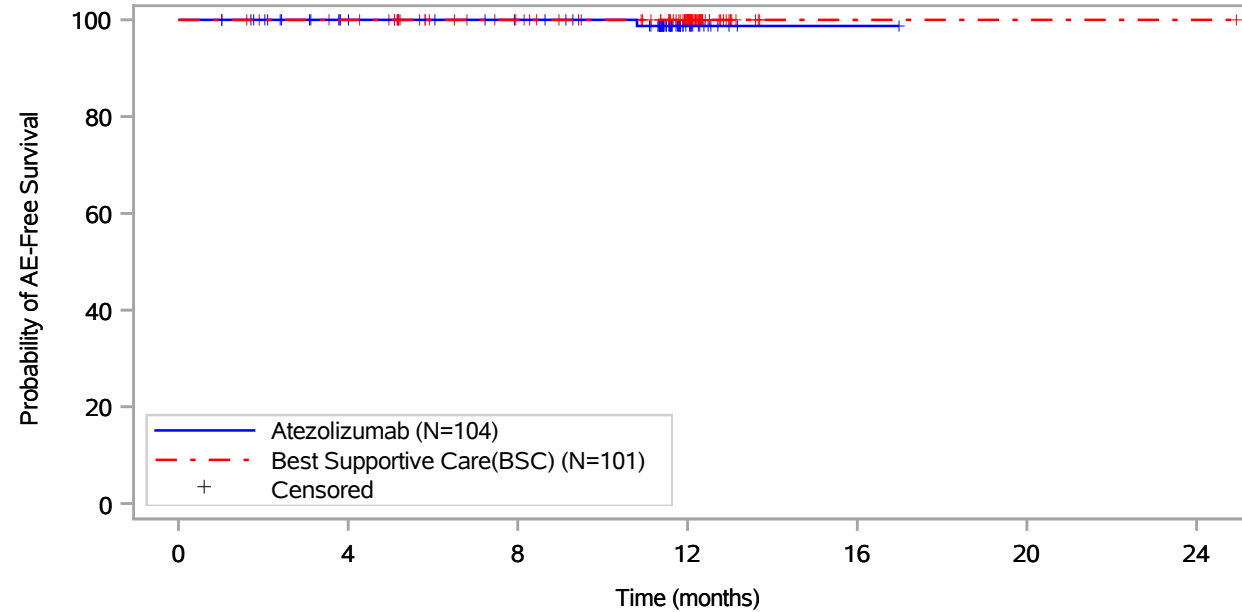
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Gastrointestinal disorders, Bowel movement irregularity



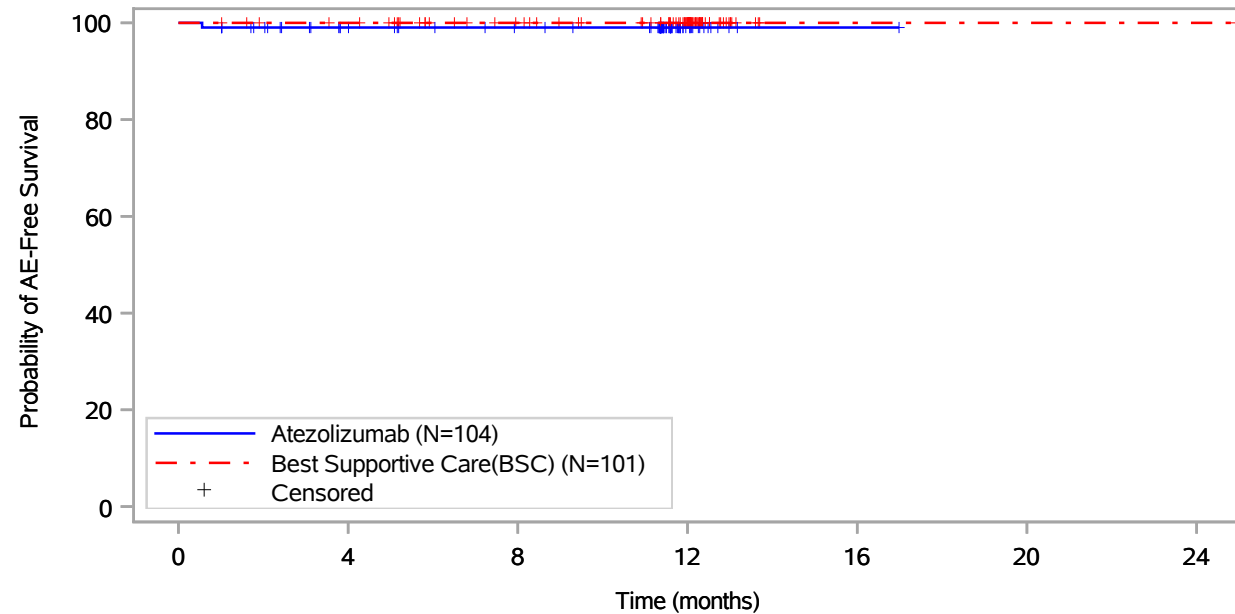
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Cheilitis



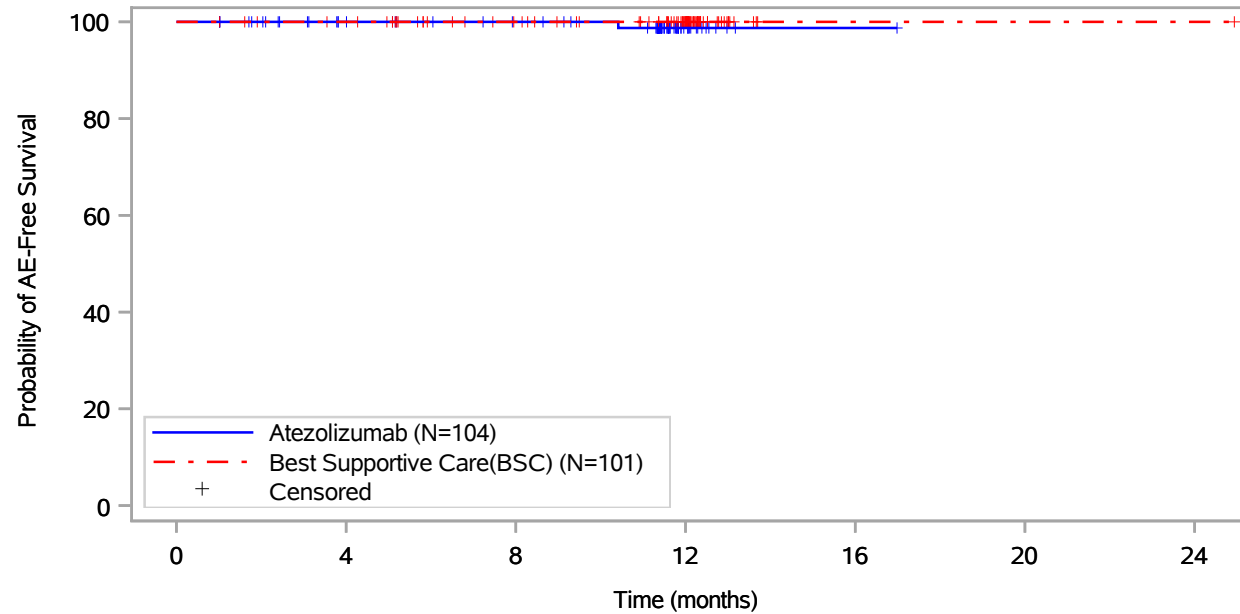
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Colitis



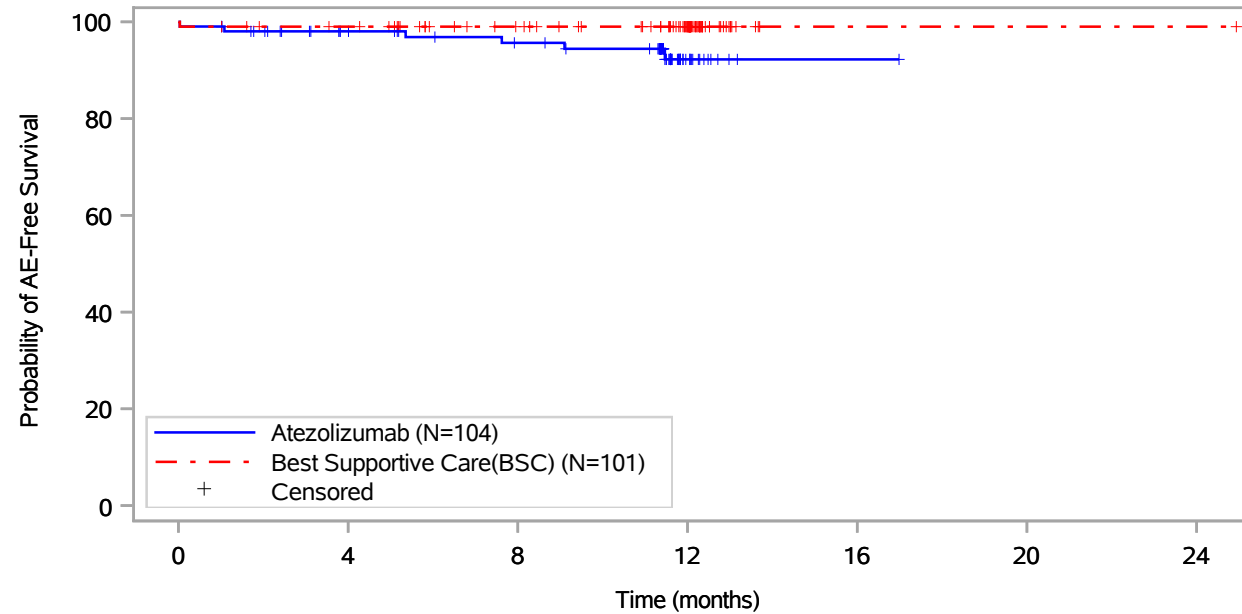
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Constipation



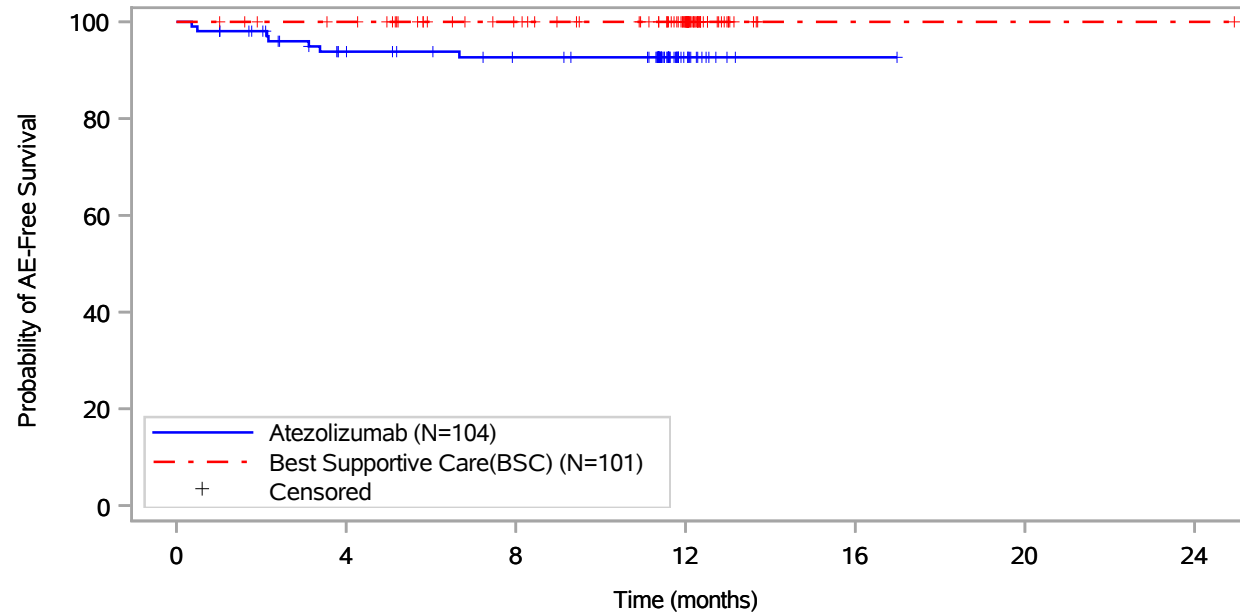
Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	84	97	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Diarrhoea



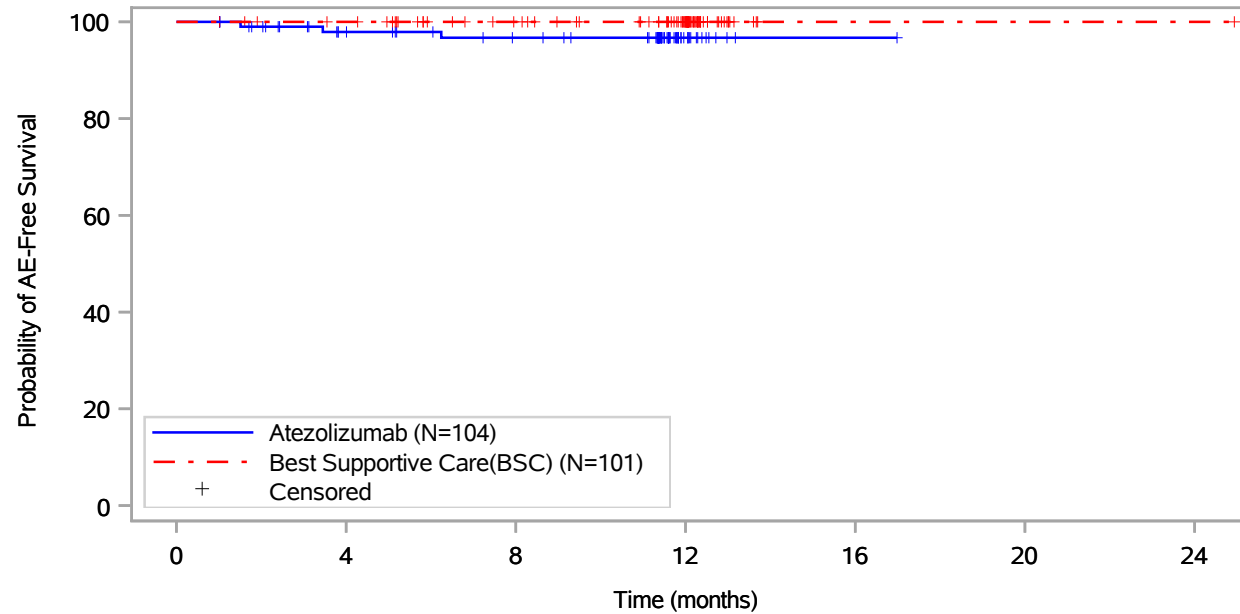
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	84	77	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	20	83	96	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Dry mouth



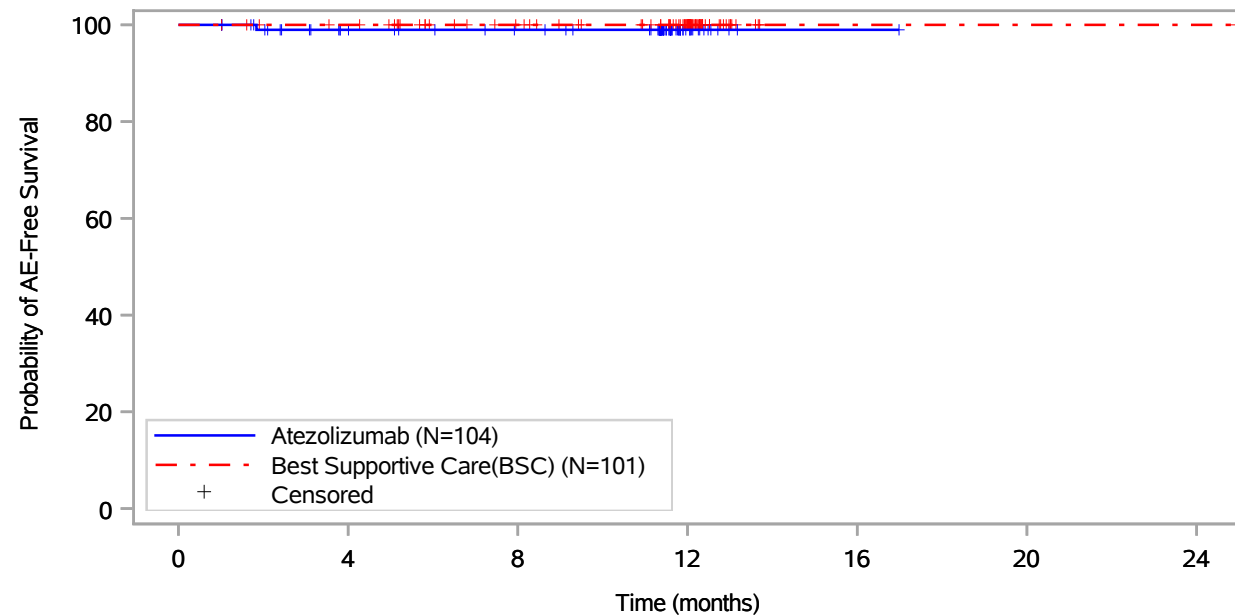
Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Dyspepsia



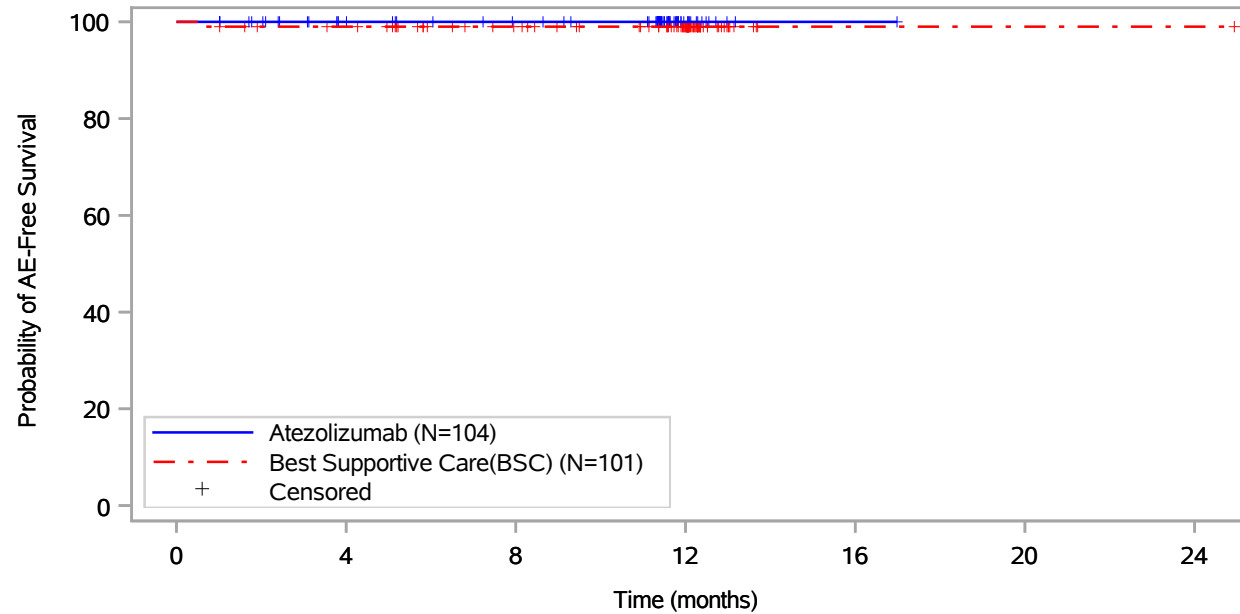
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Dysphagia



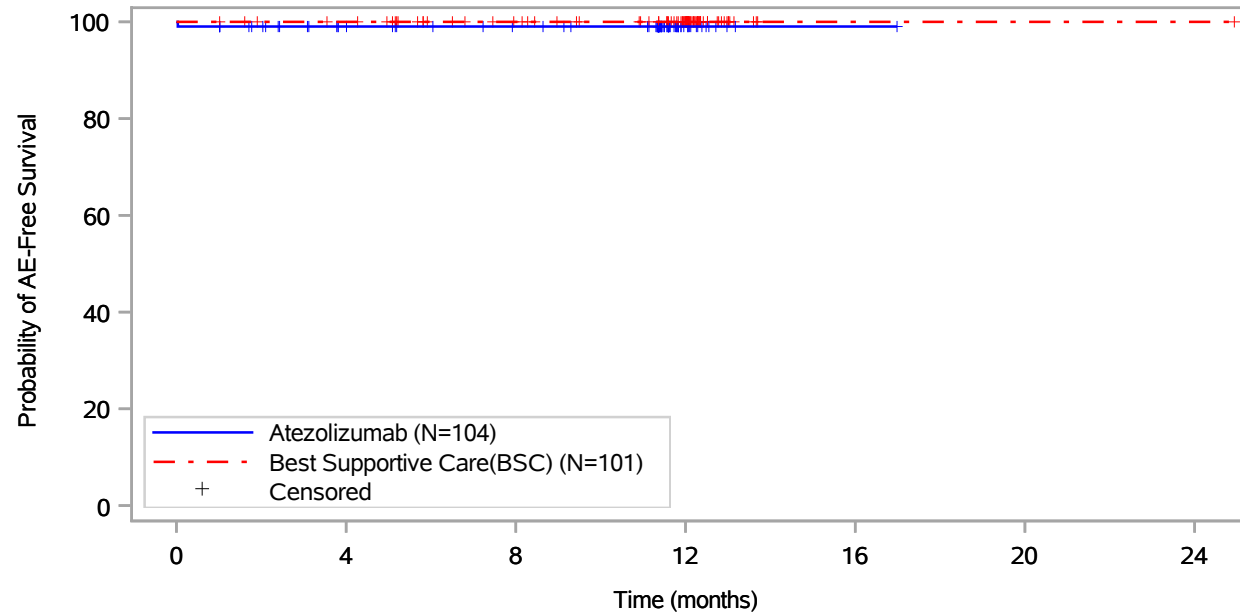
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Faeces soft



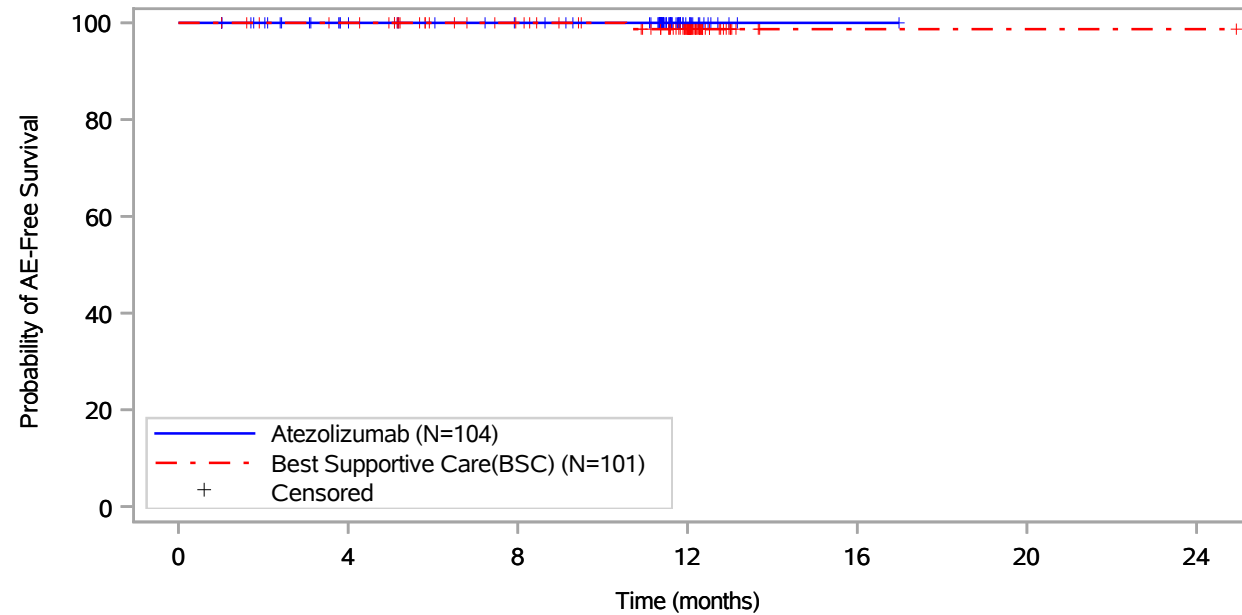
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Flatulence



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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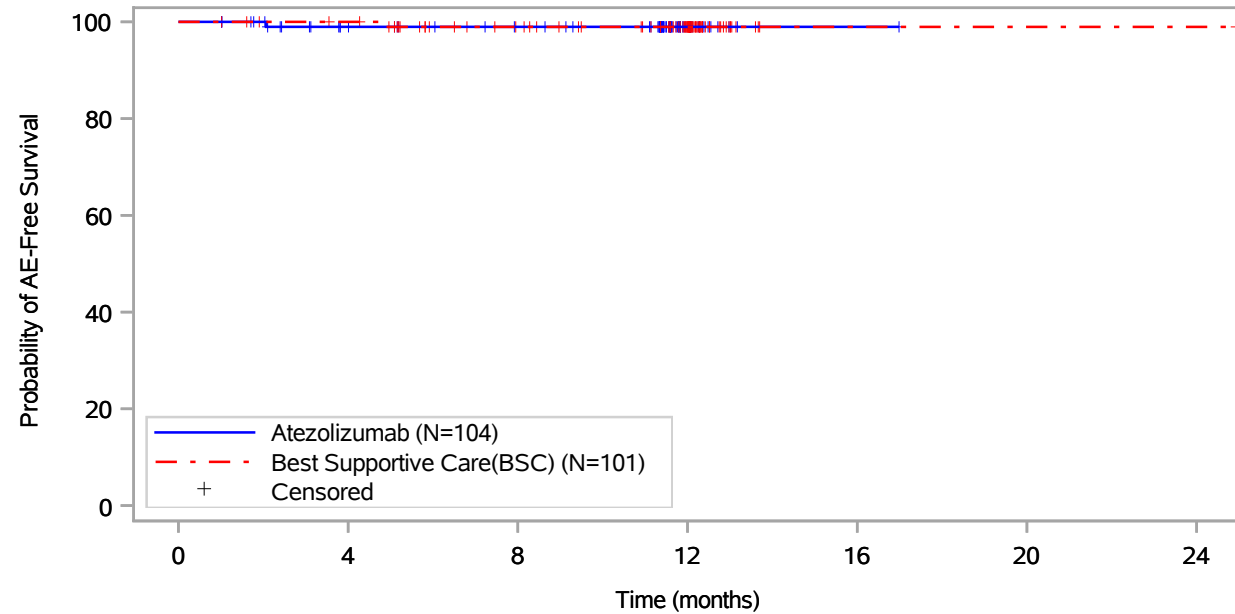
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Gastrooesophageal reflux disease



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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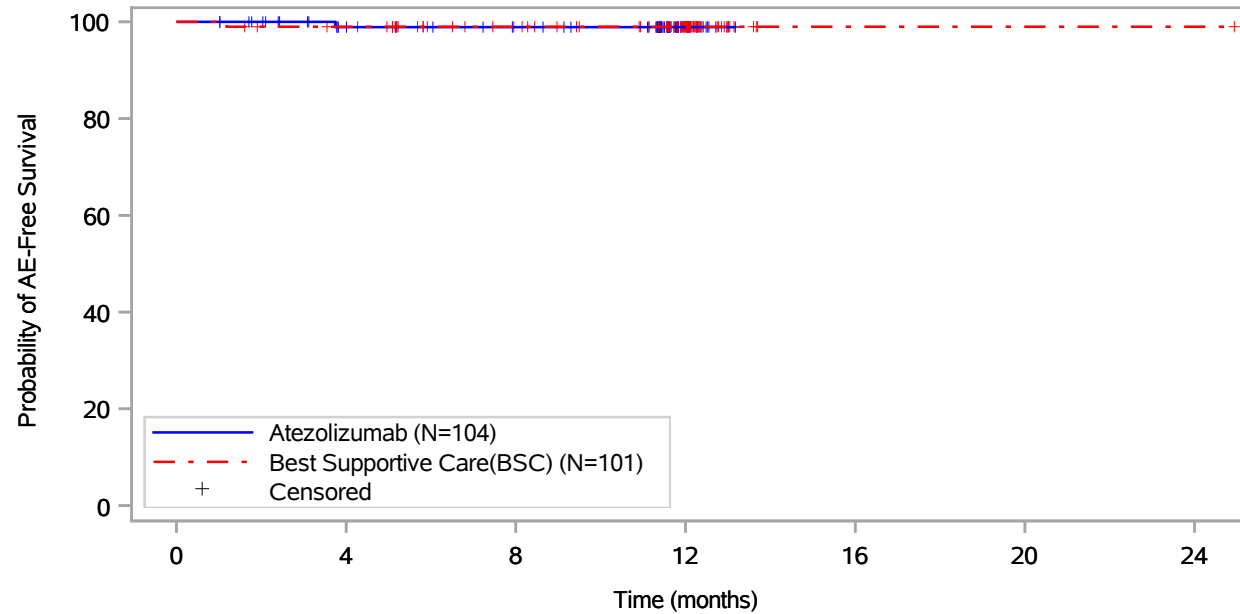
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Gastrointestinal disorders, Haemorrhoids



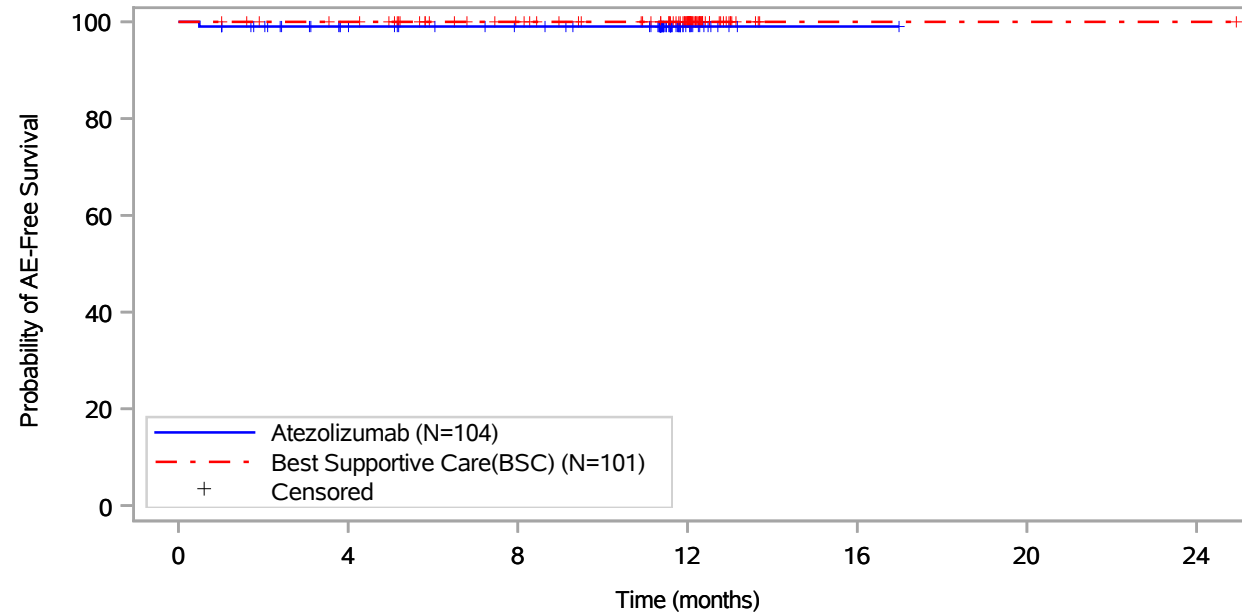
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Hyperaesthesia teeth



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

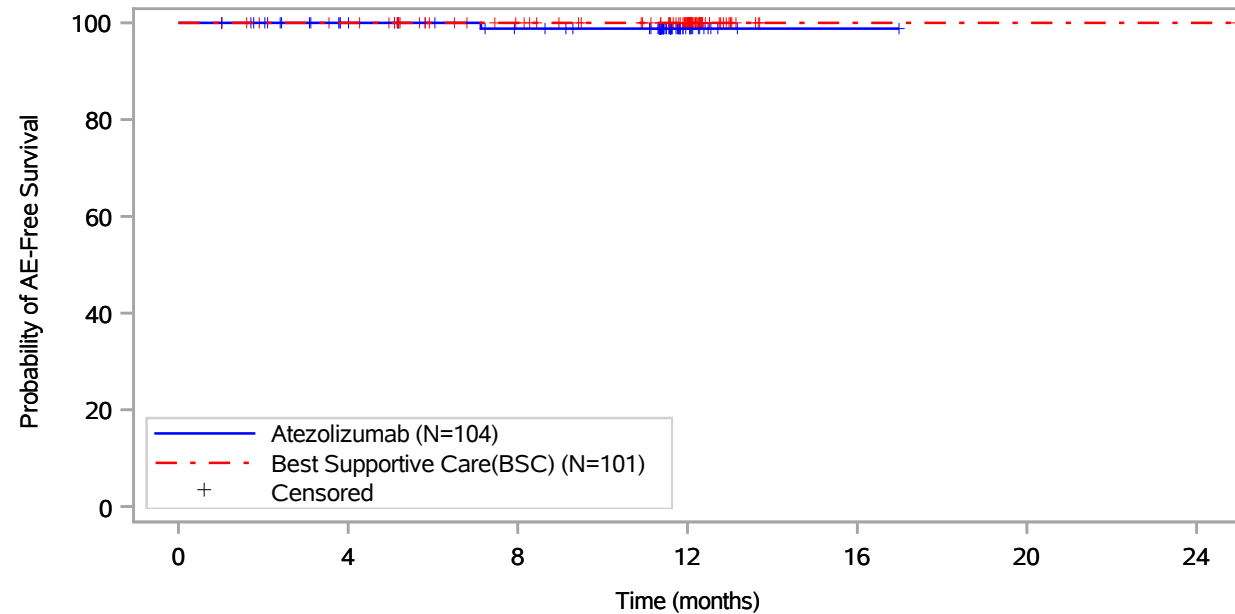
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Gastrointestinal disorders, Large intestine polyp



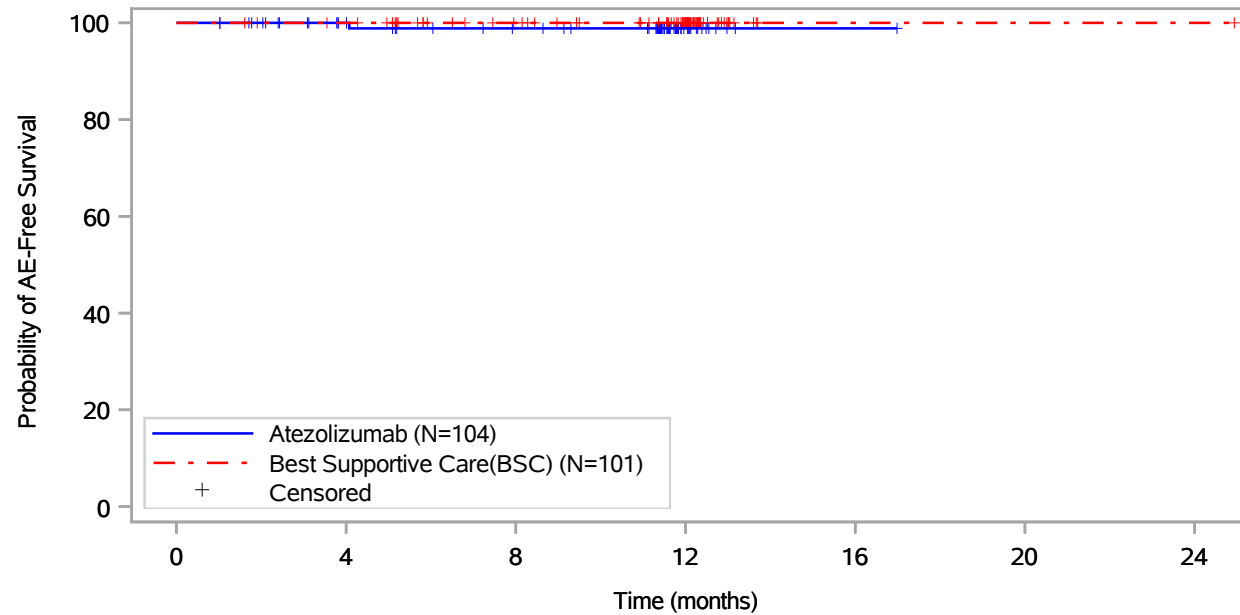
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Mouth ulceration



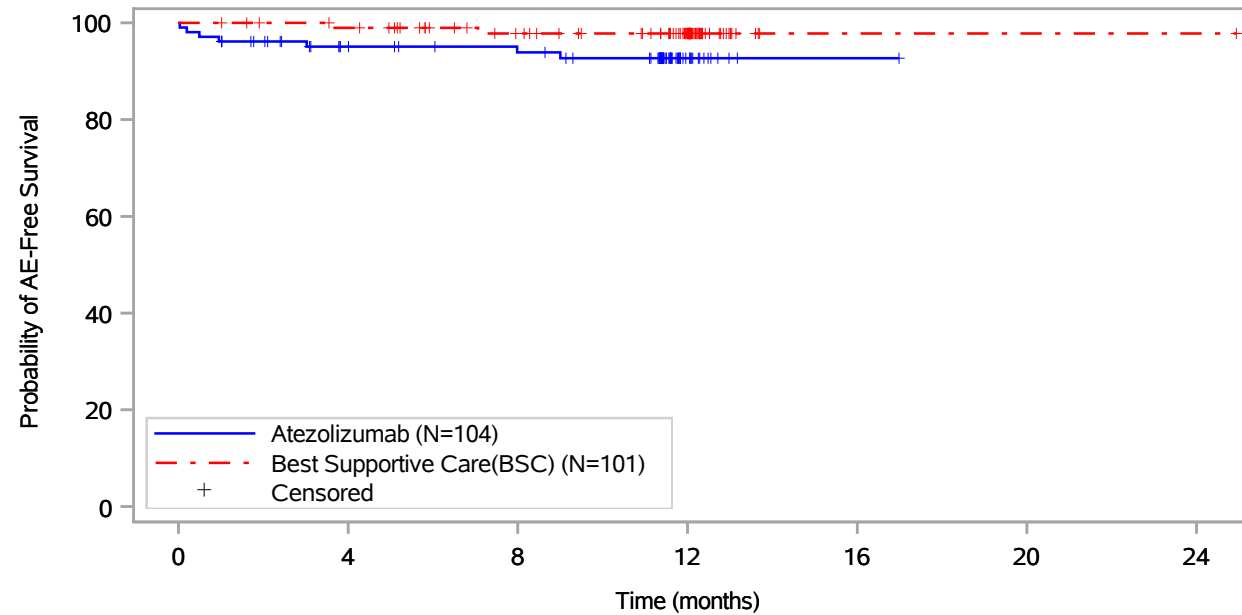
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Nausea



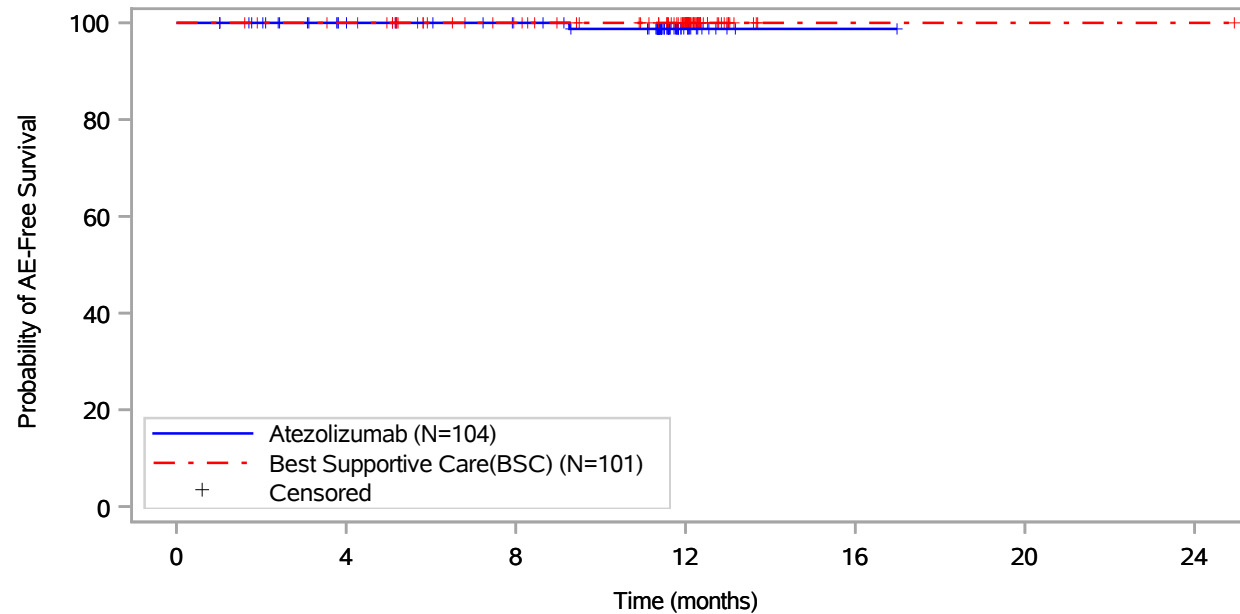
Patients at risk							
Atezolizumab (N=104)	104	84	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	19	83	96	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Stomatitis



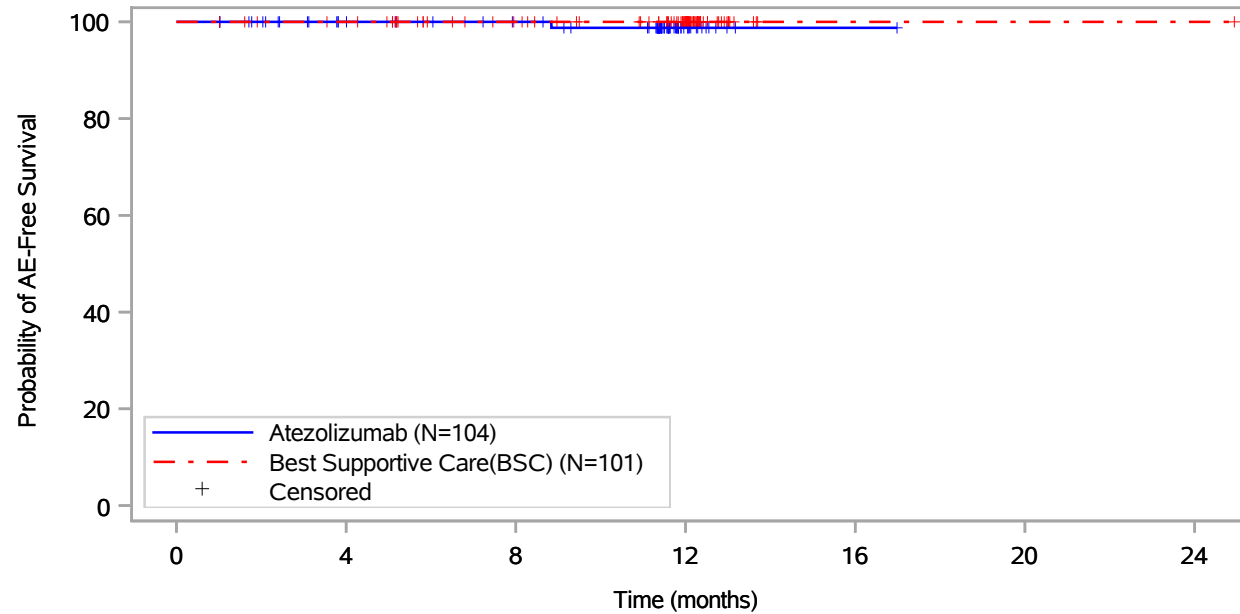
Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Toothache



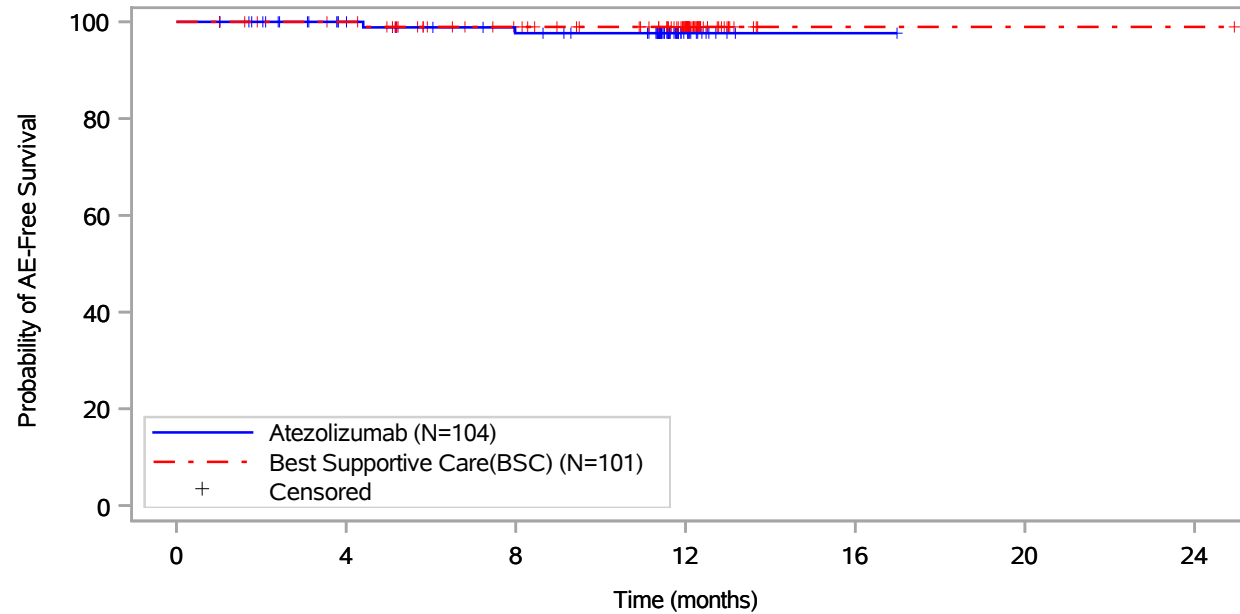
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Vomiting



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

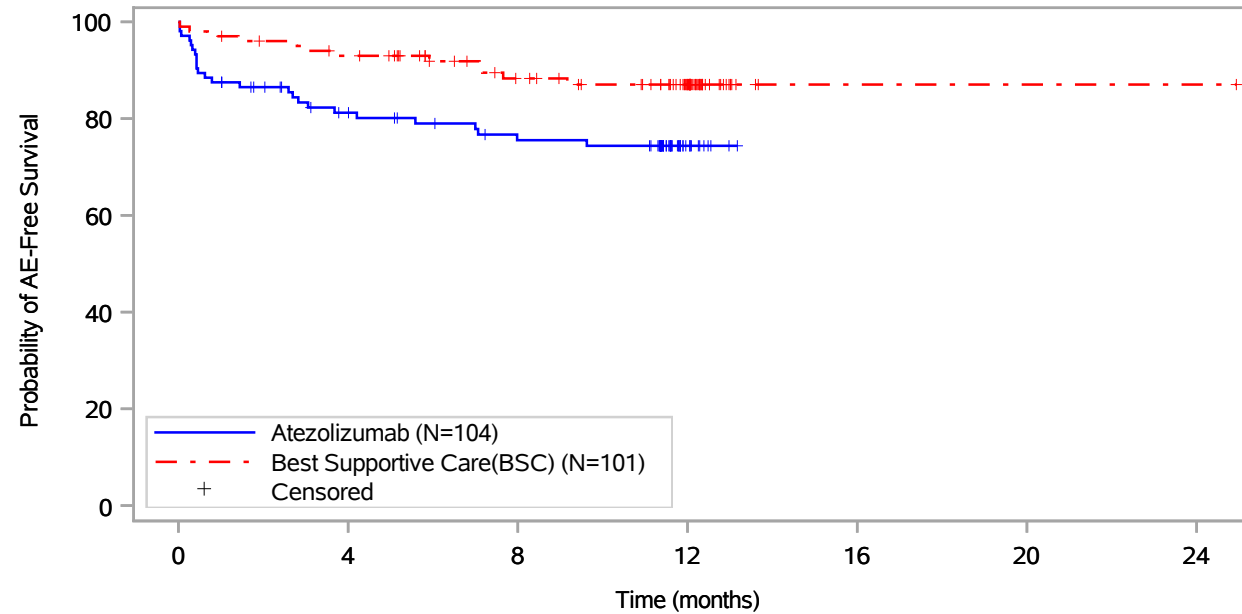
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	75	65	11	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	91	73	47	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	10	15	68	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	17	42	88	88	88

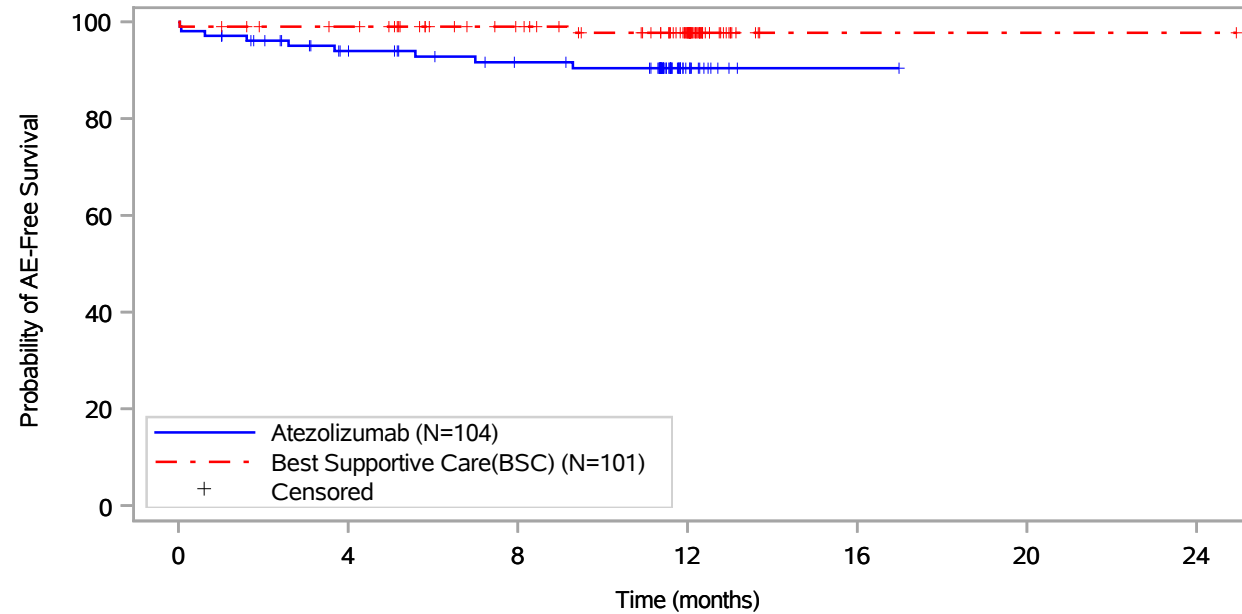
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 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Asthenia



Patients at risk							
Atezolizumab (N=104)	104	85	76	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	13	20	82	94	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98

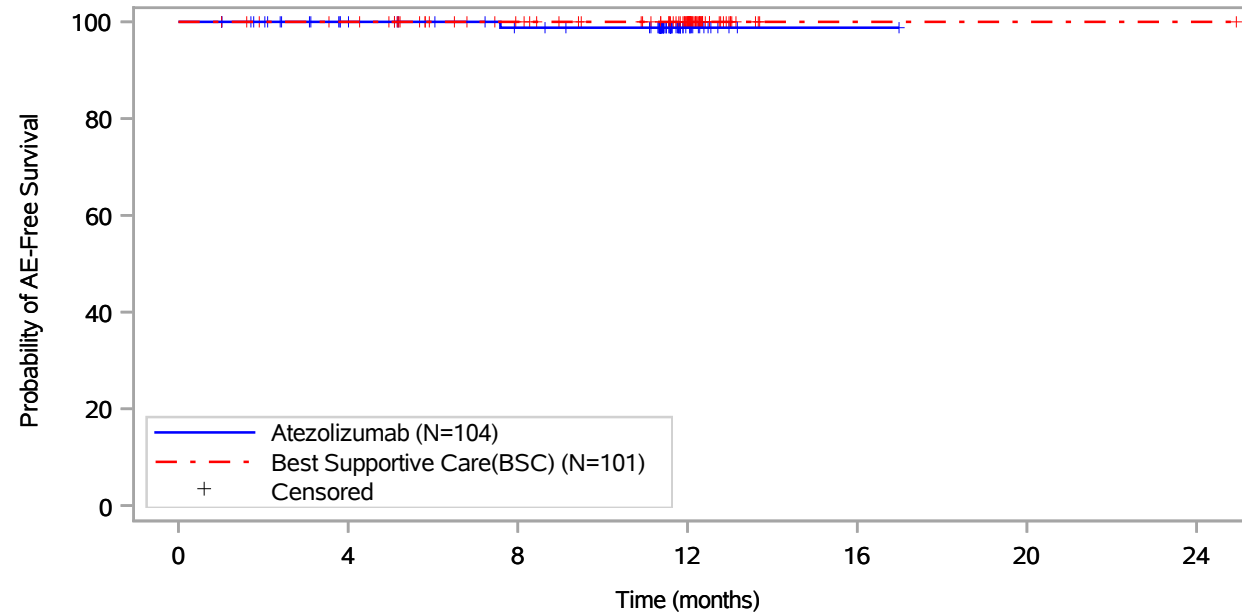
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Catheter site haematoma



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

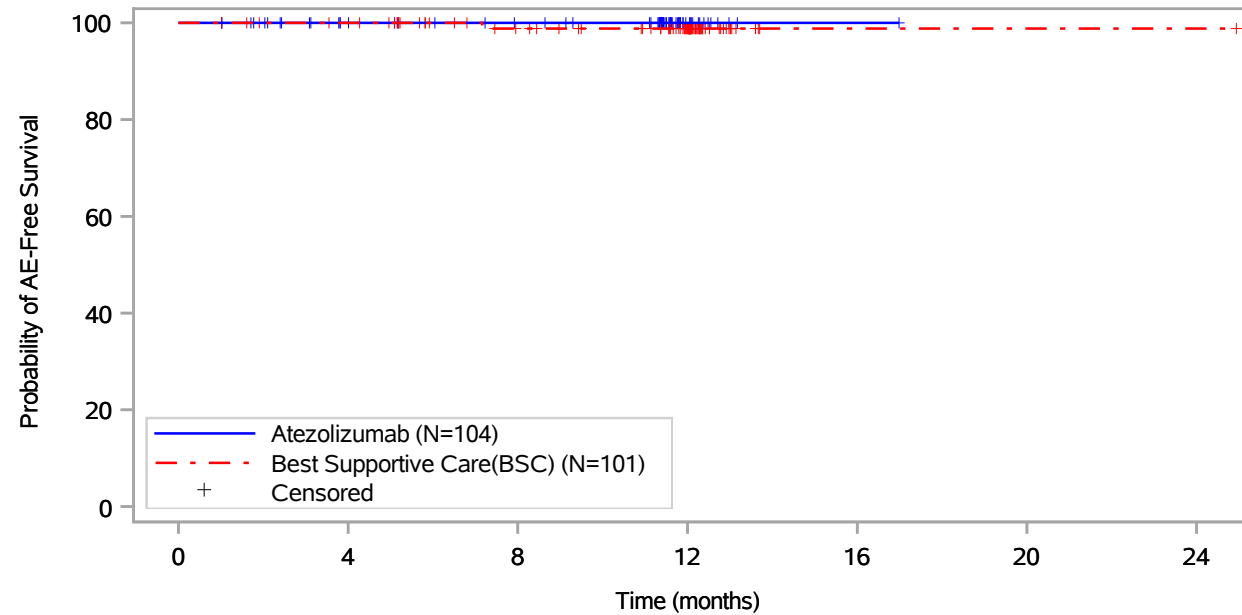
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Chest discomfort



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99	99

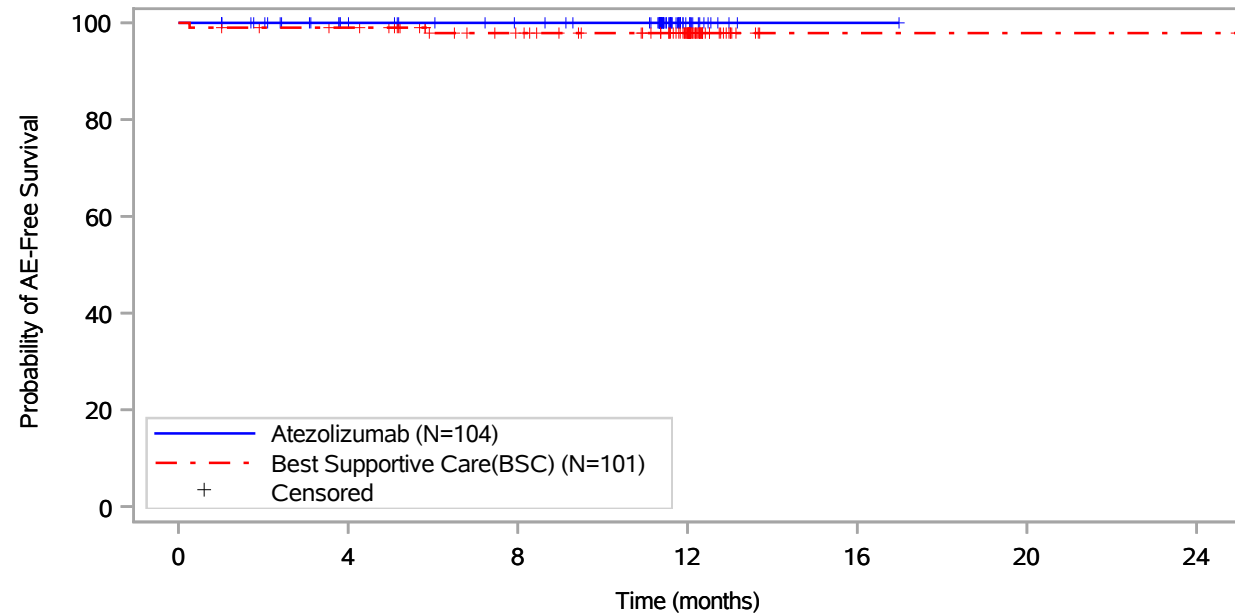
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Chest pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	17	45	98	98	98	98

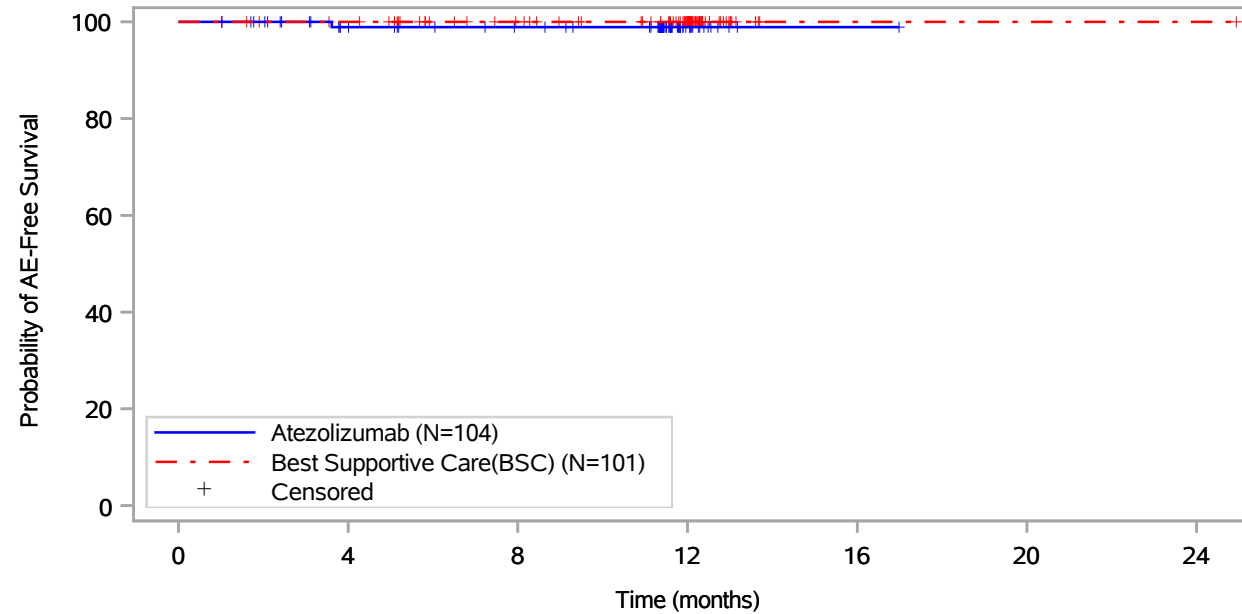
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Chills



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

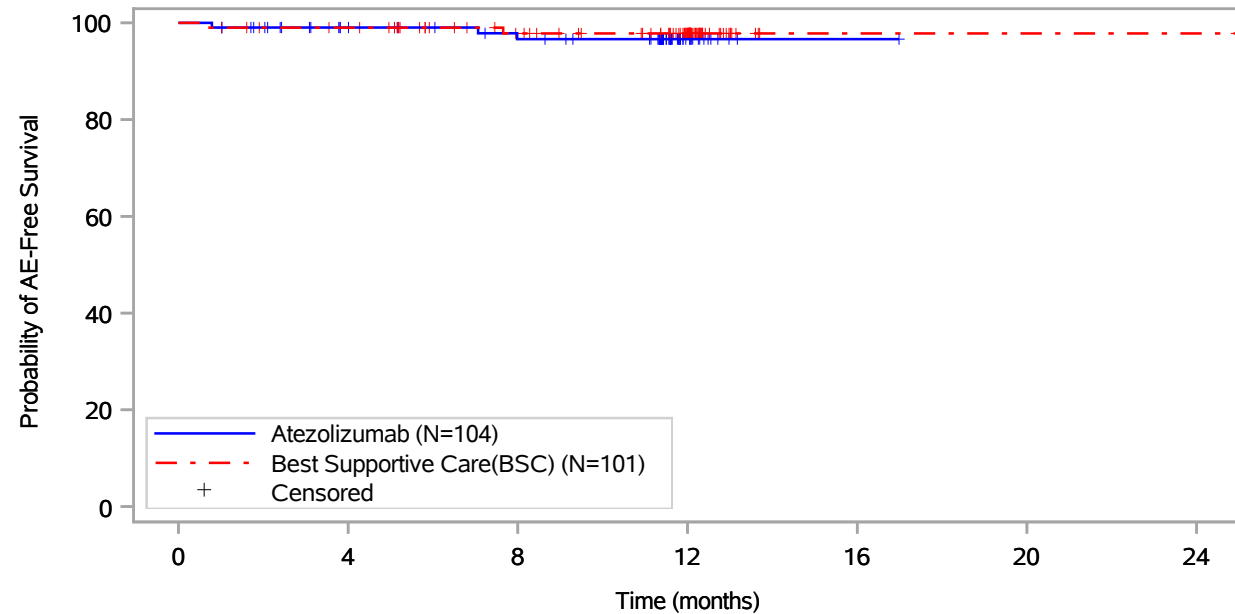
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

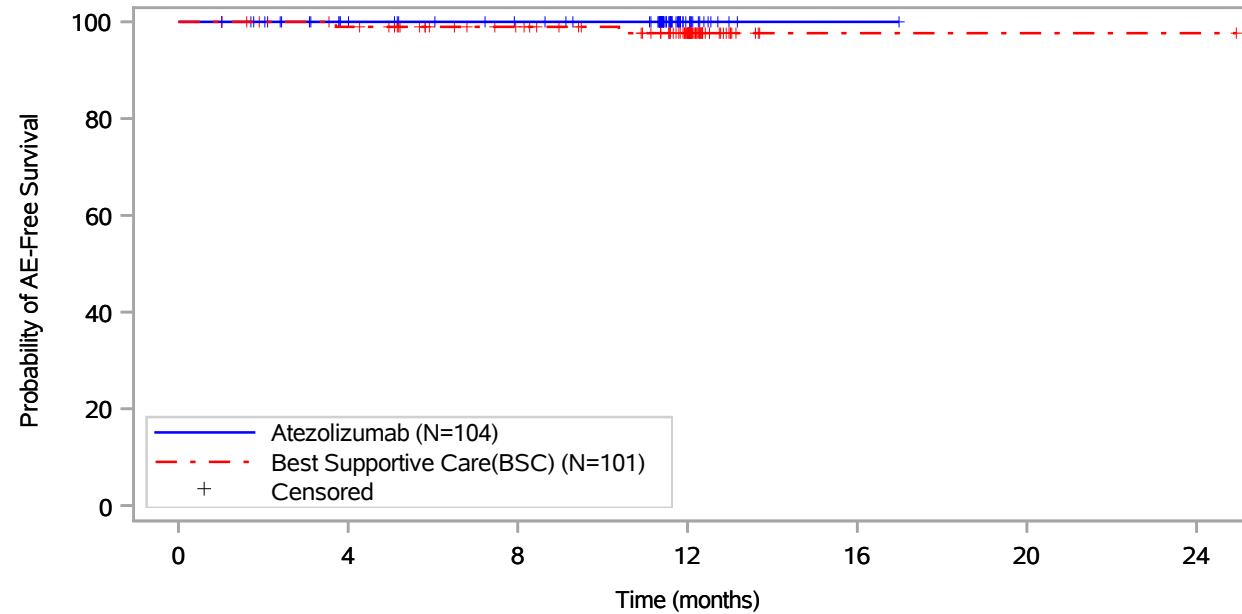
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Gait disturbance



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	53	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	98	98	98

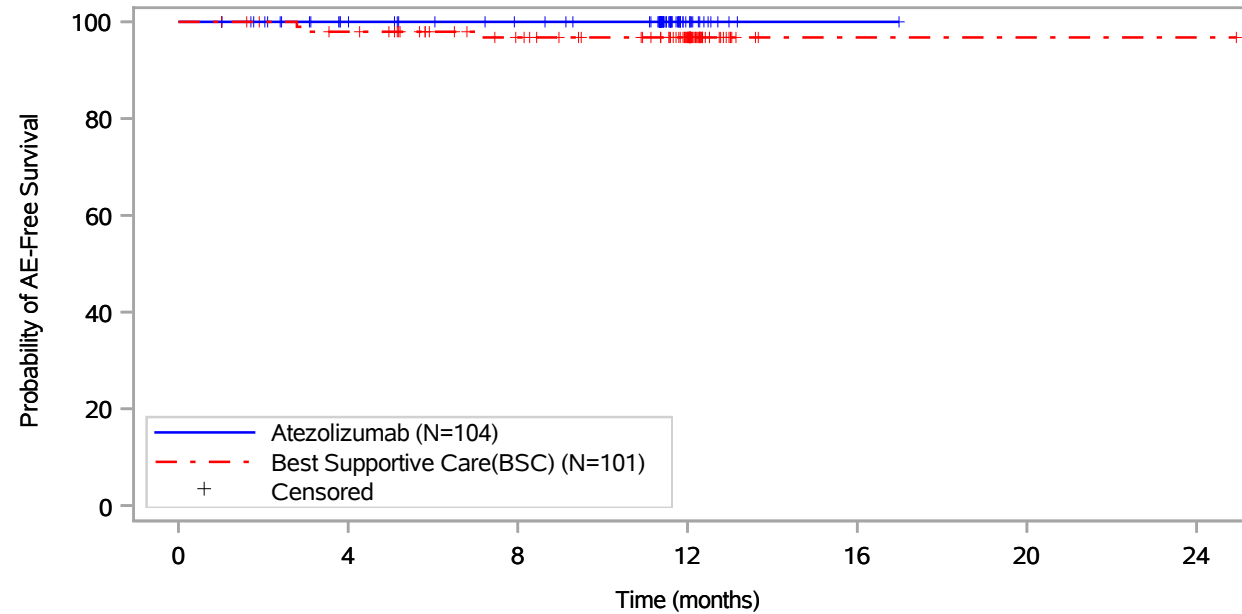
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	95	80	53	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	97	97	97

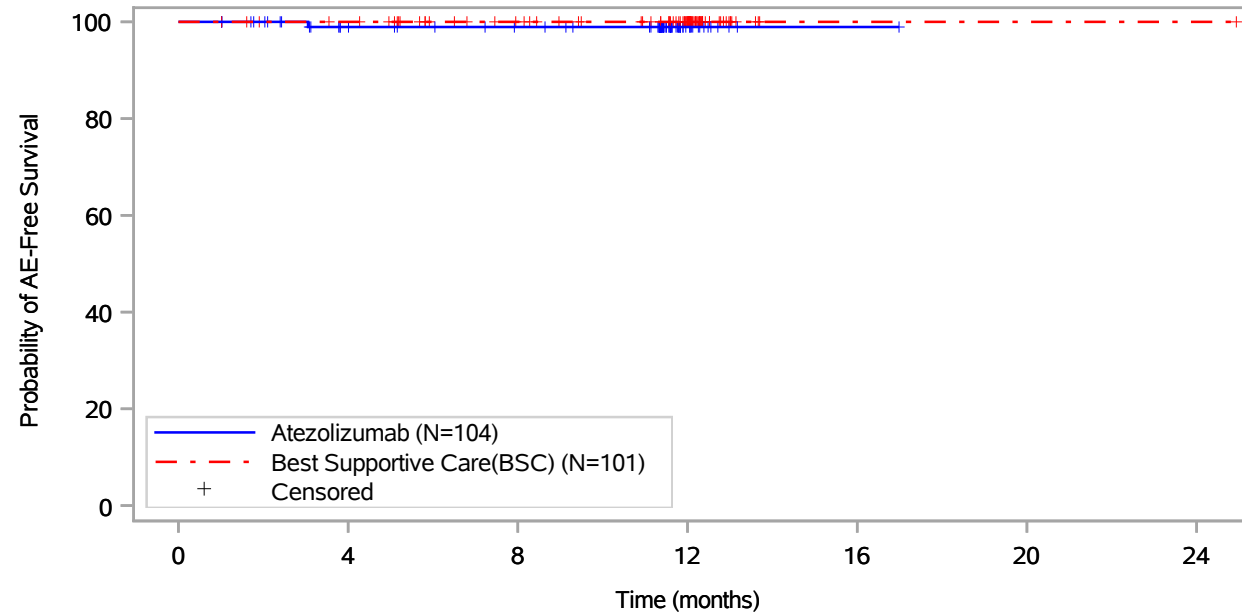
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Oedema



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

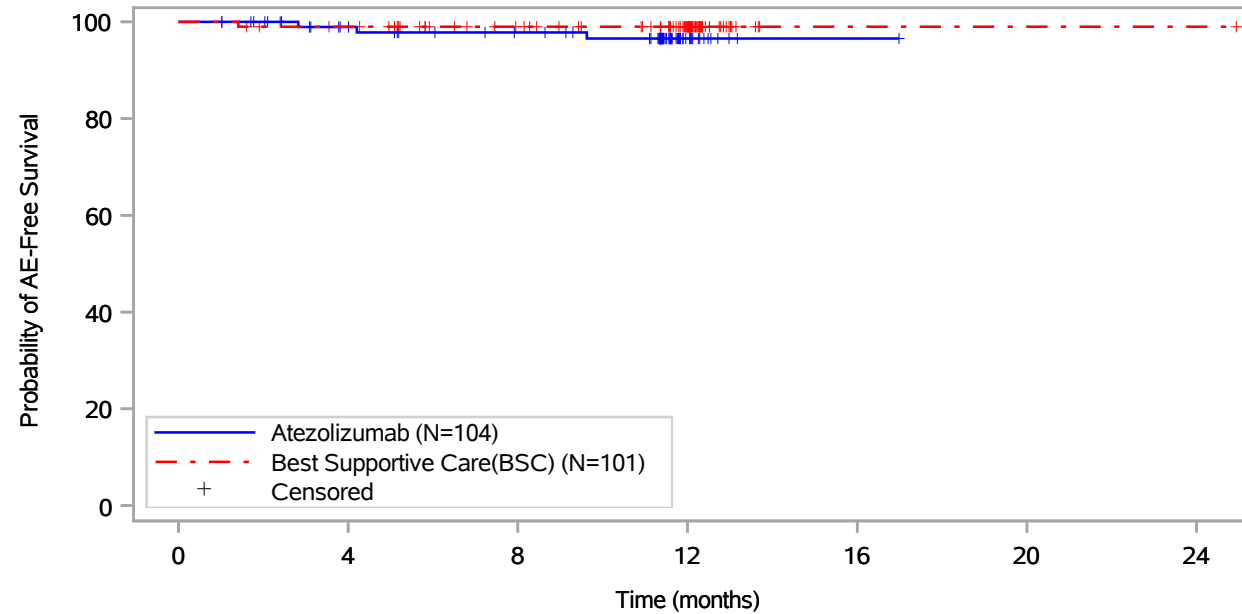
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Oedema peripheral



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	87	100	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

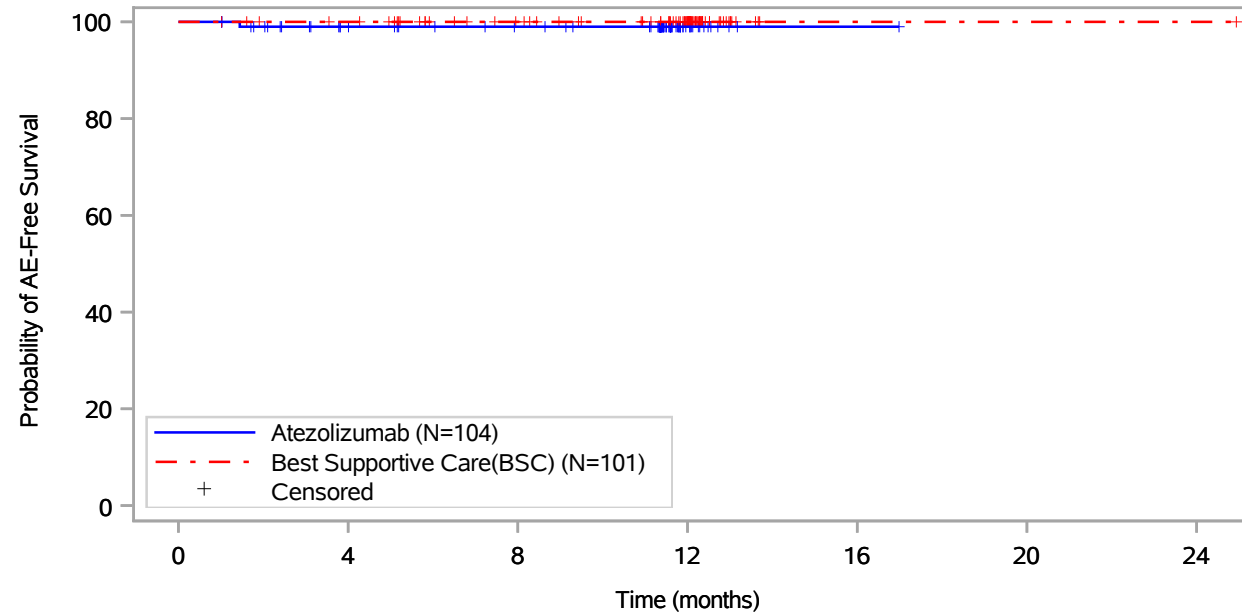
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

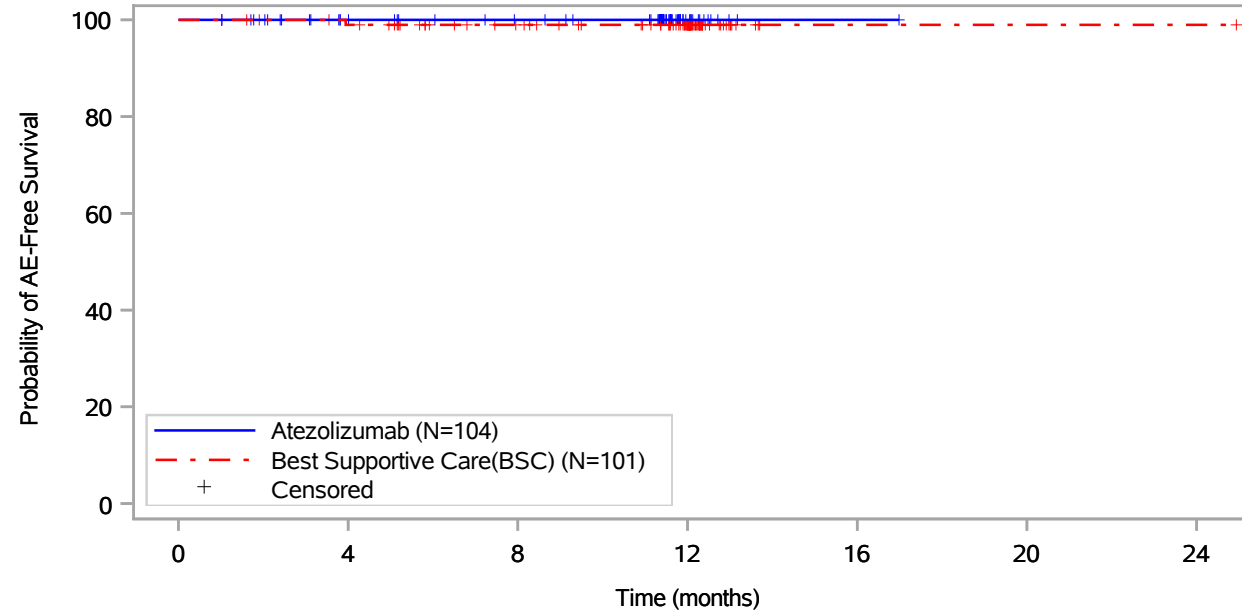
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Peripheral swelling



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

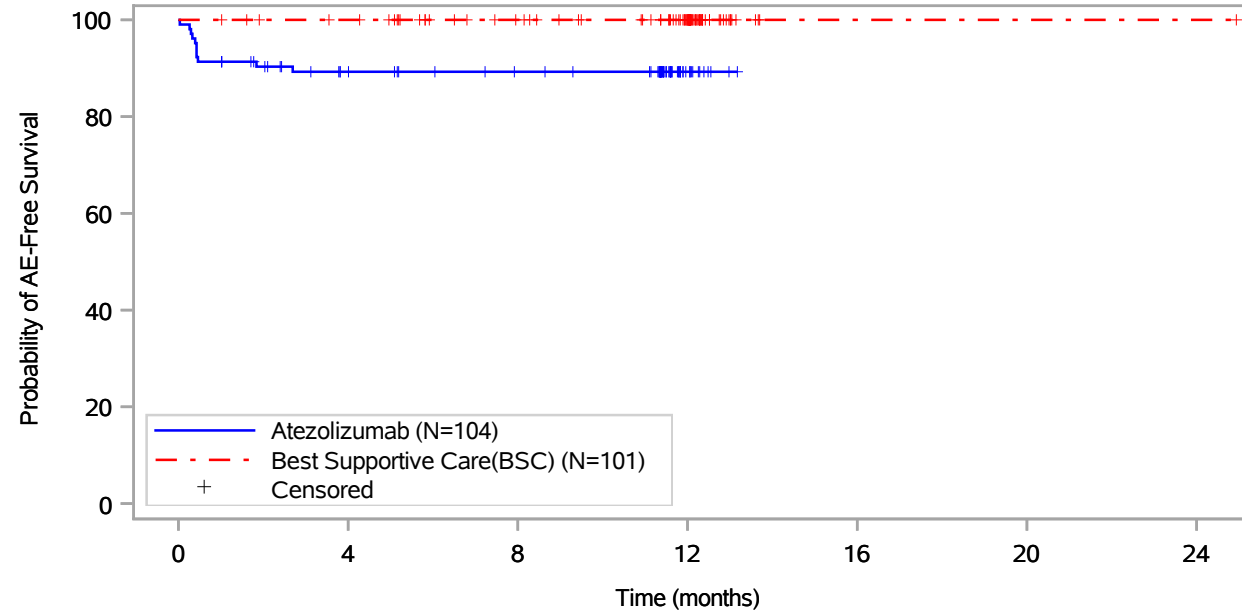
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pyrexia



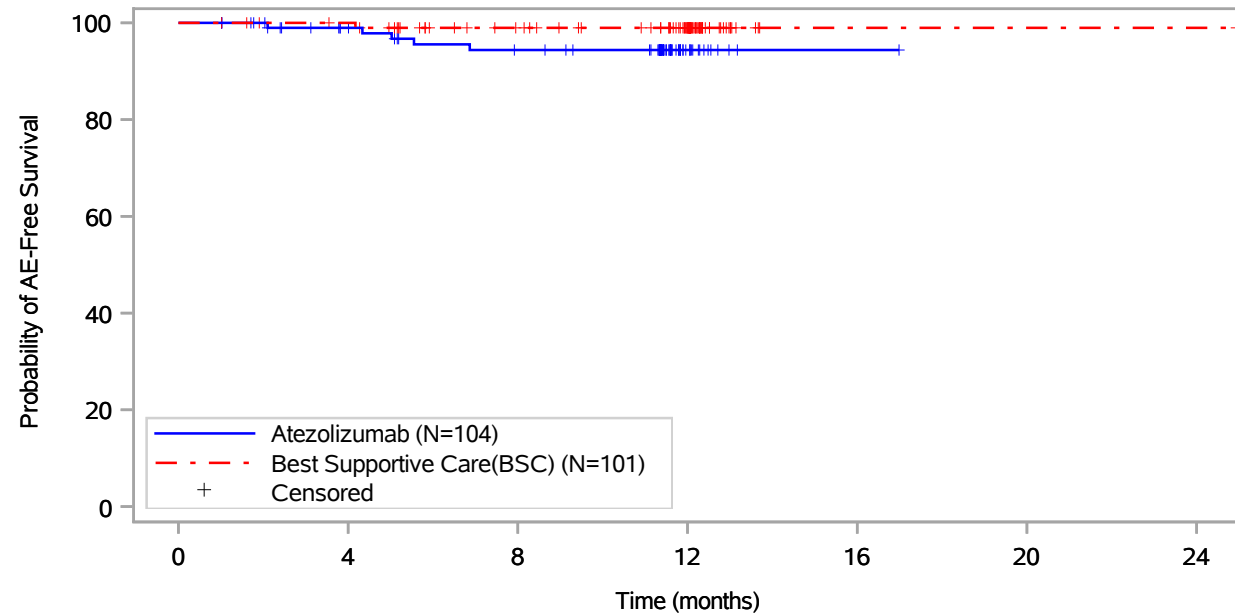
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	80	73	12	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	13	20	81	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, All



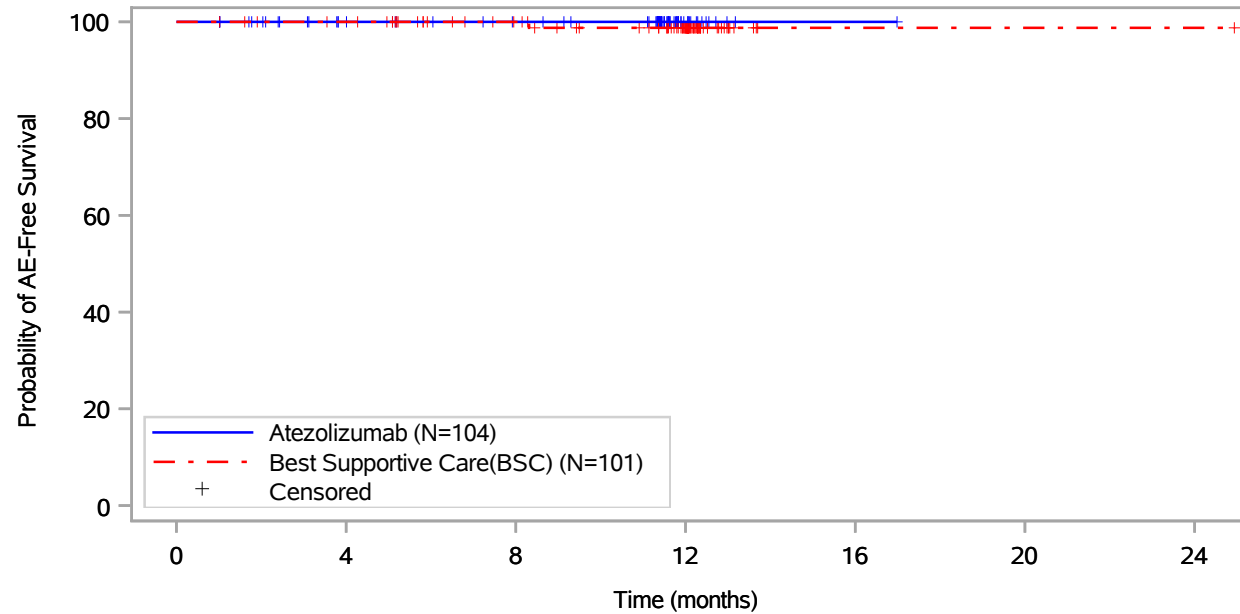
Patients at risk							
Atezolizumab (N=104)	104	89	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	85	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Cholestasis



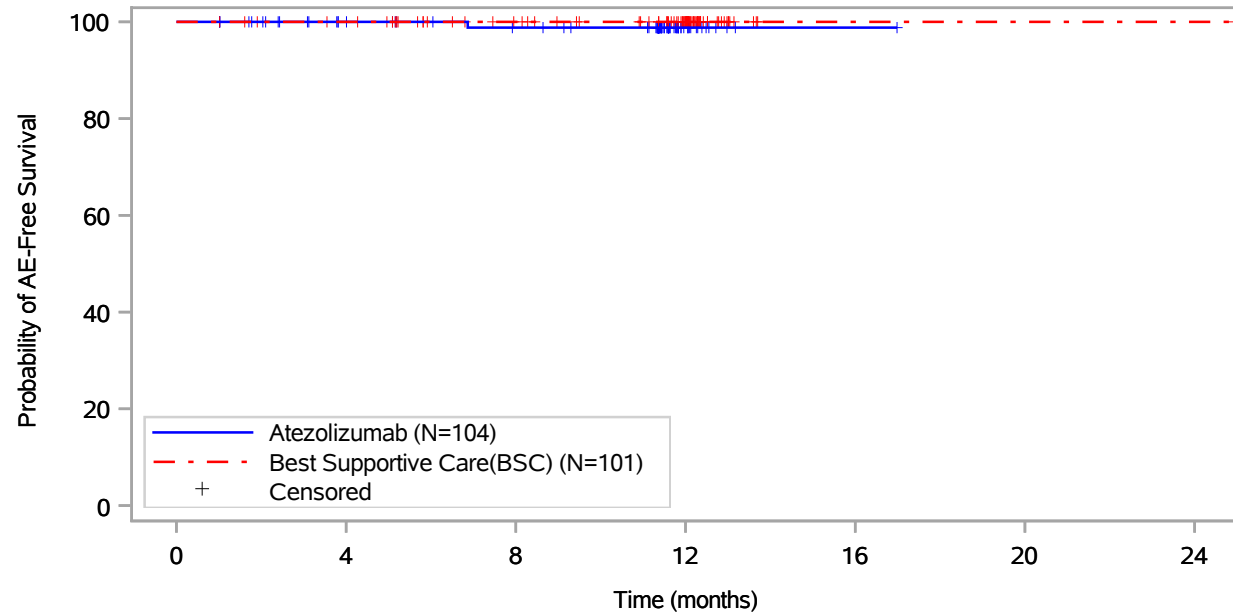
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Drug-induced liver injury



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

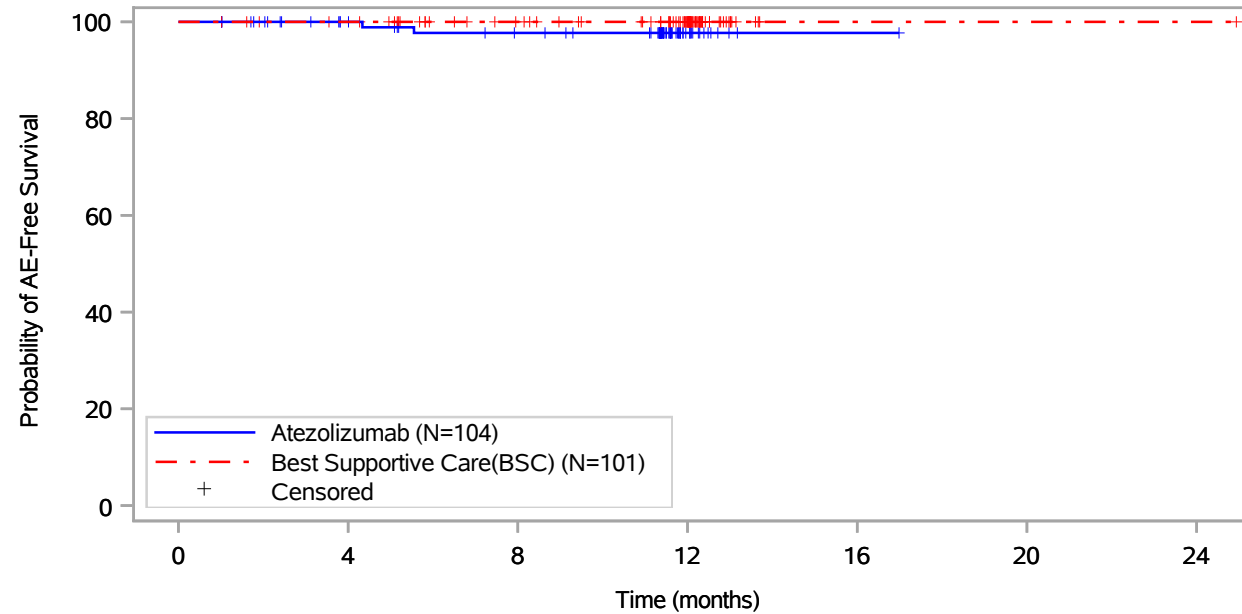
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



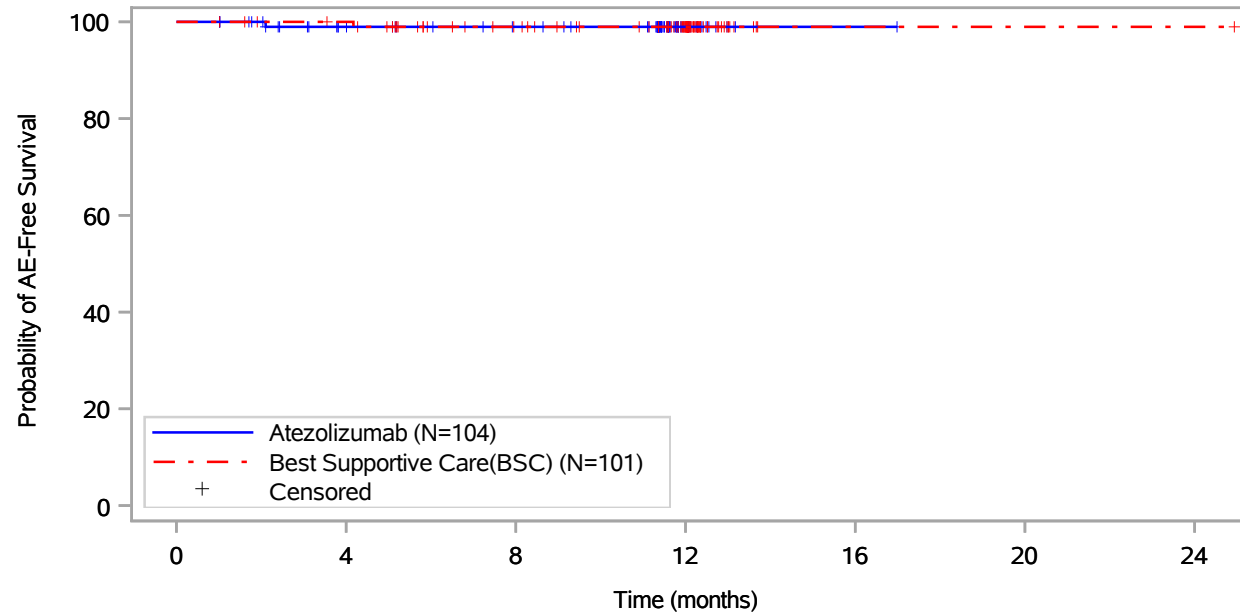
Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Hepatic steatosis



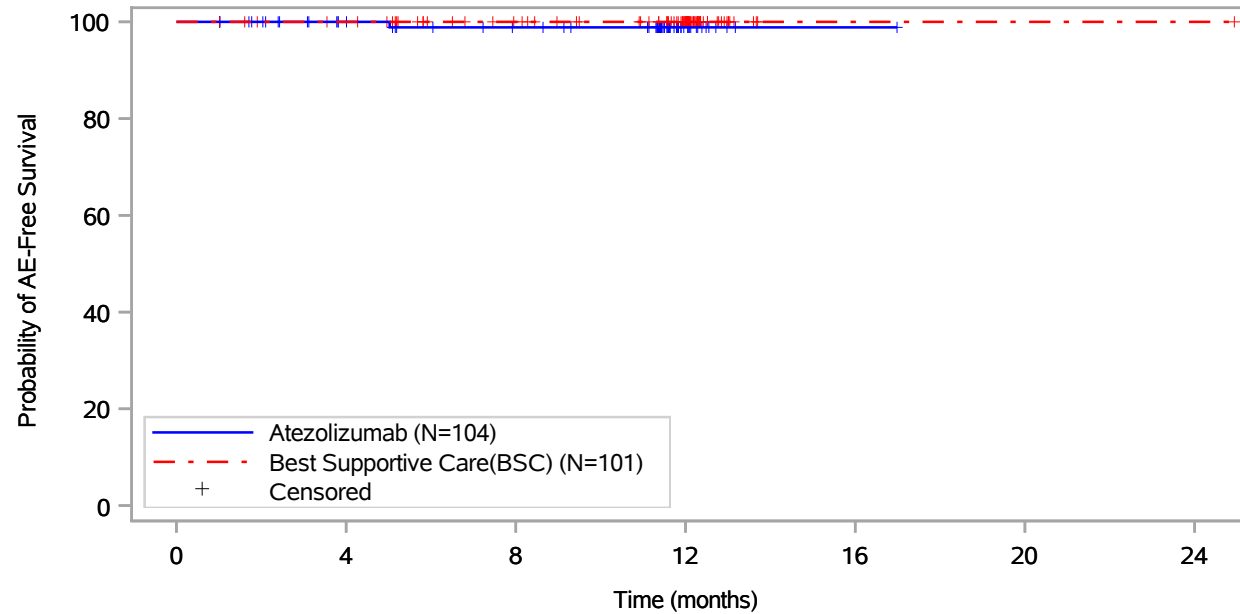
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Hyperbilirubinaemia



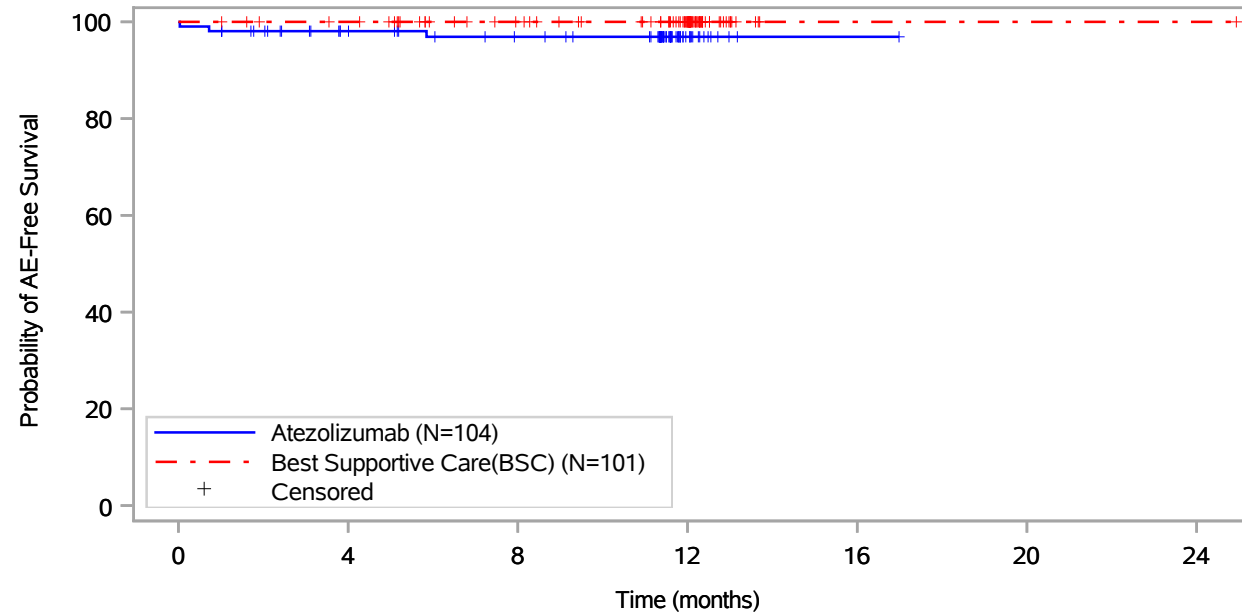
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Immune system disorders, All



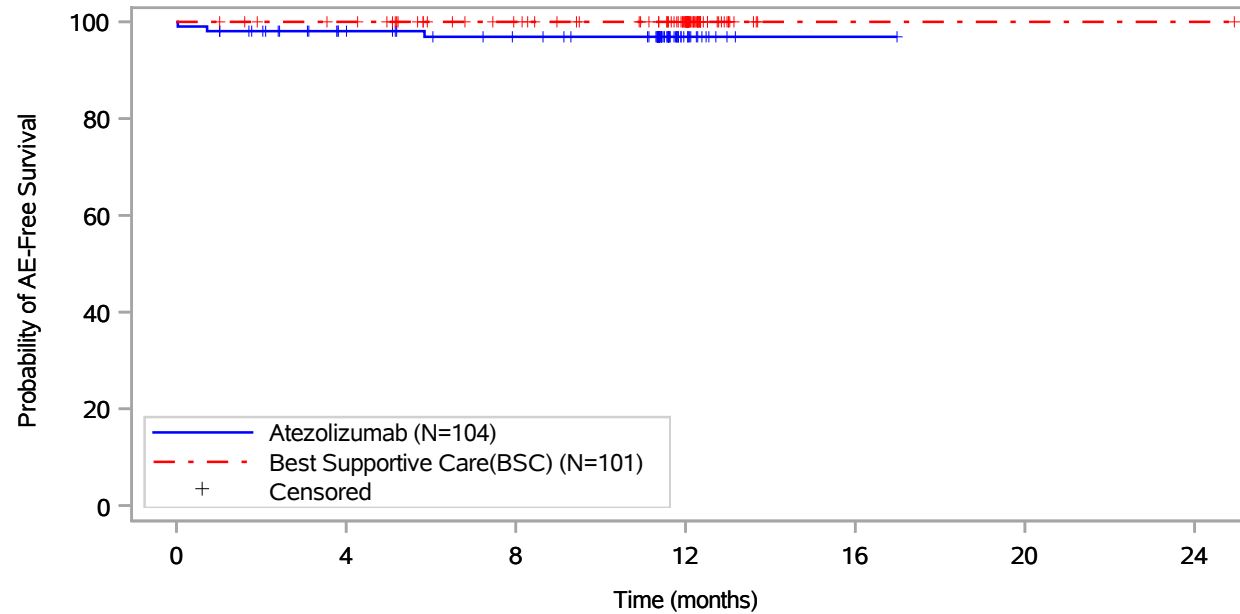
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	87	100	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Immune system disorders, Hypersensitivity



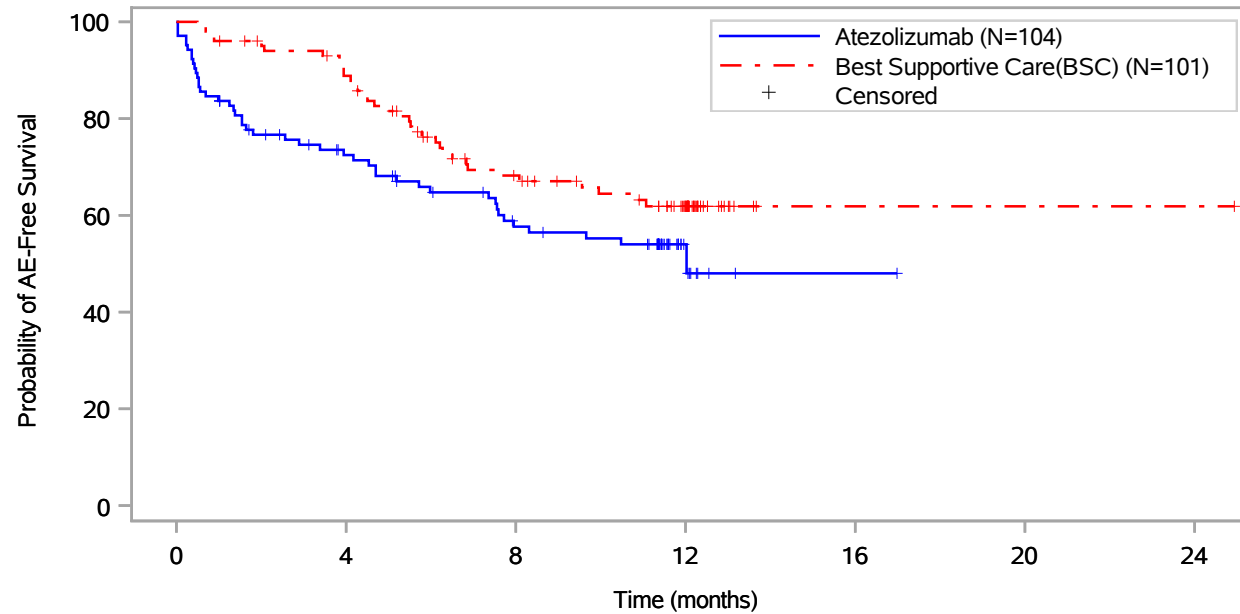
Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, All



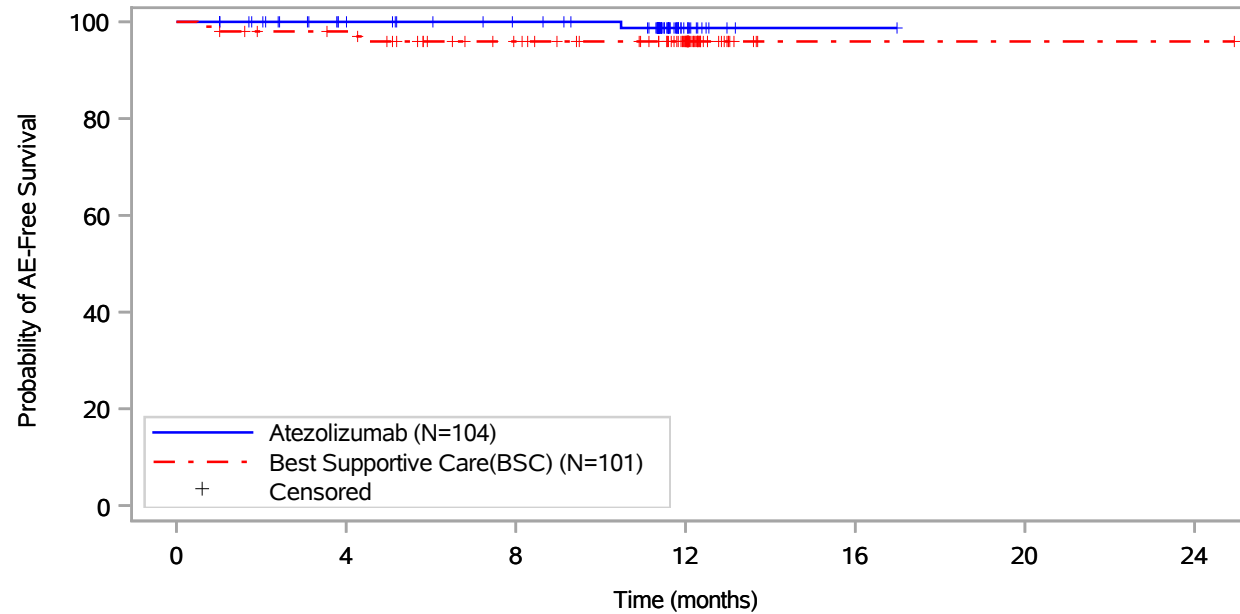
Patients at risk							
Atezolizumab (N=104)	104	67	48	9	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	86	58	35	1	1	1
Patients censored							
Atezolizumab (N=104)	0	9	15	51	58	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	13	31	65	65	65

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Bronchitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	95	81	53	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	16	44	96	96	96

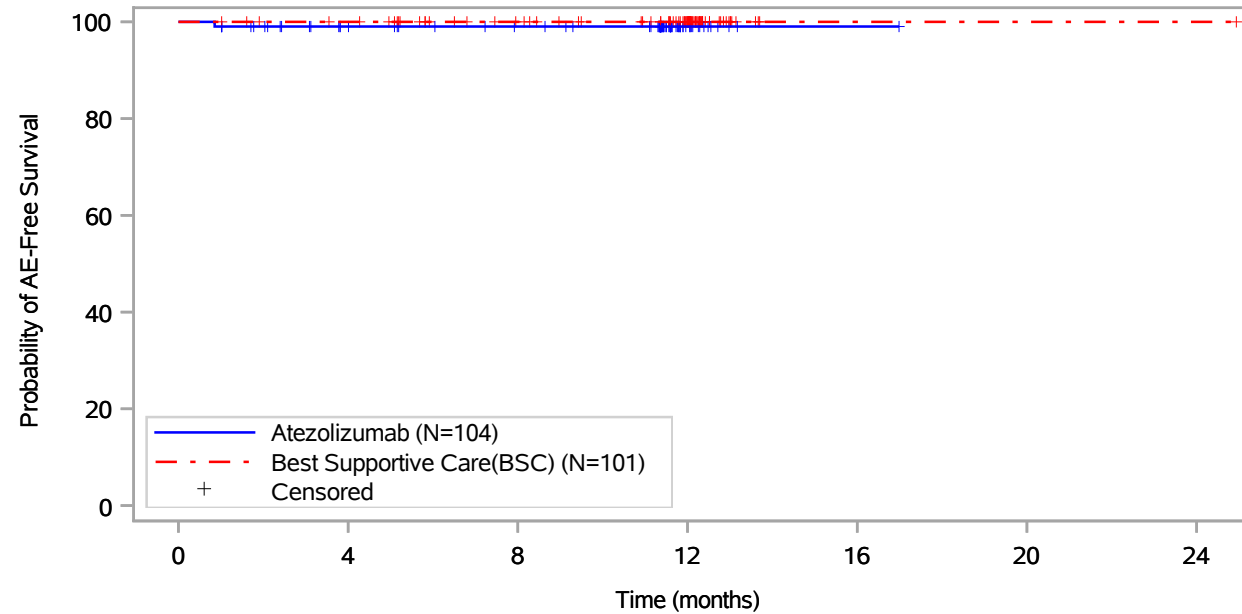
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Candida infection



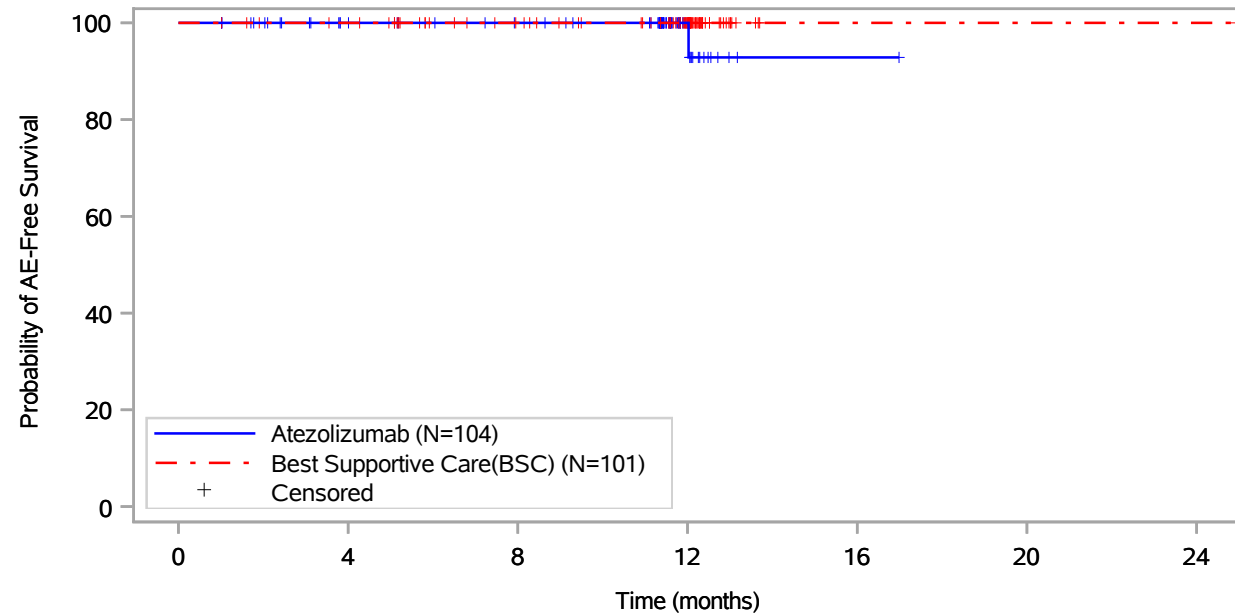
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Cellulitis



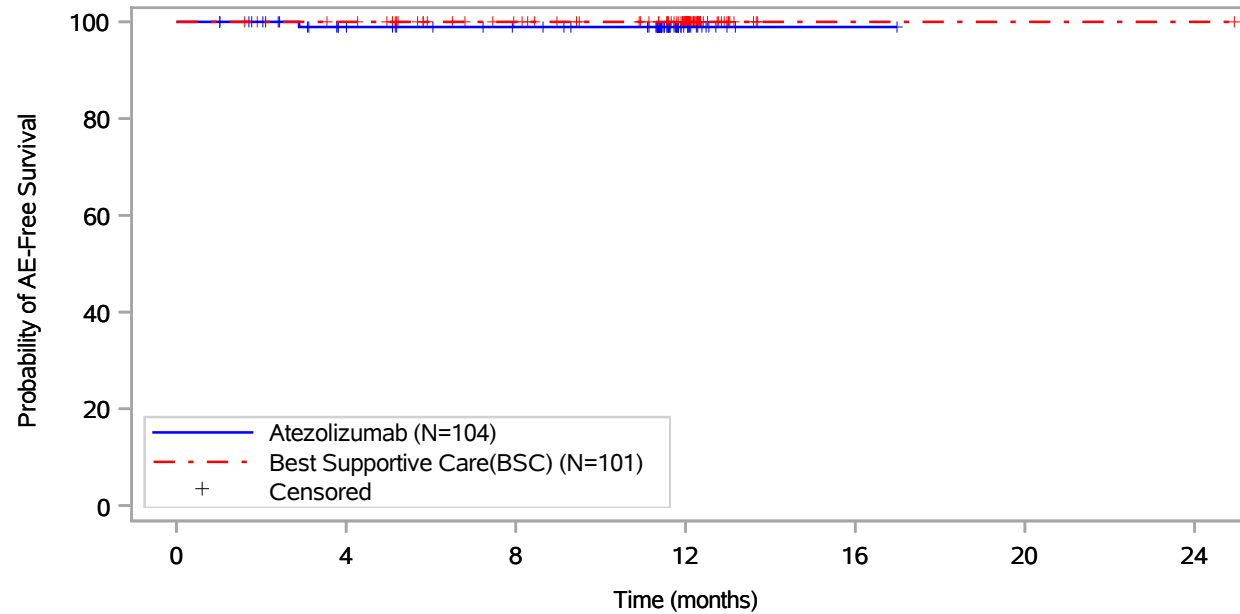
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Conjunctivitis



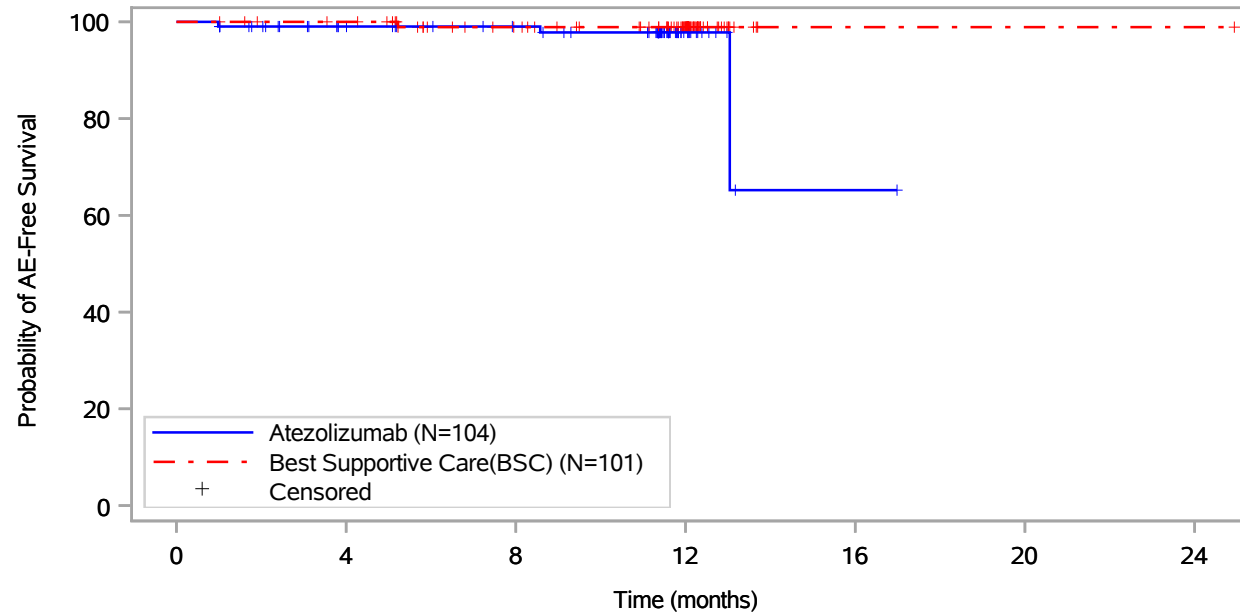
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Cystitis



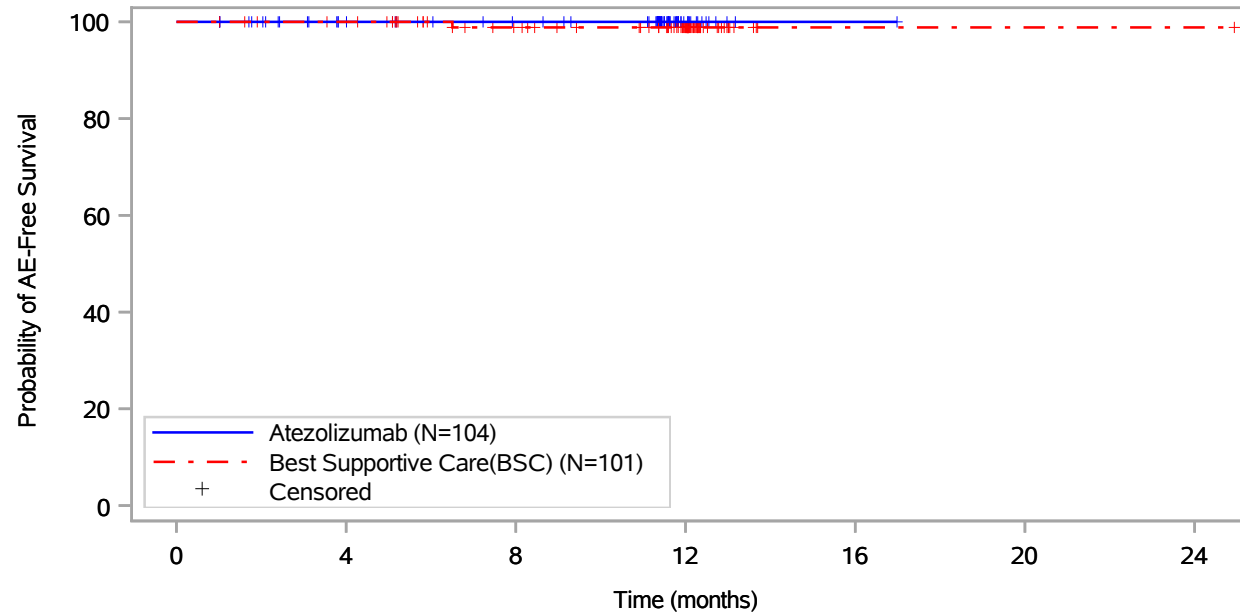
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	88	100	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Empyema



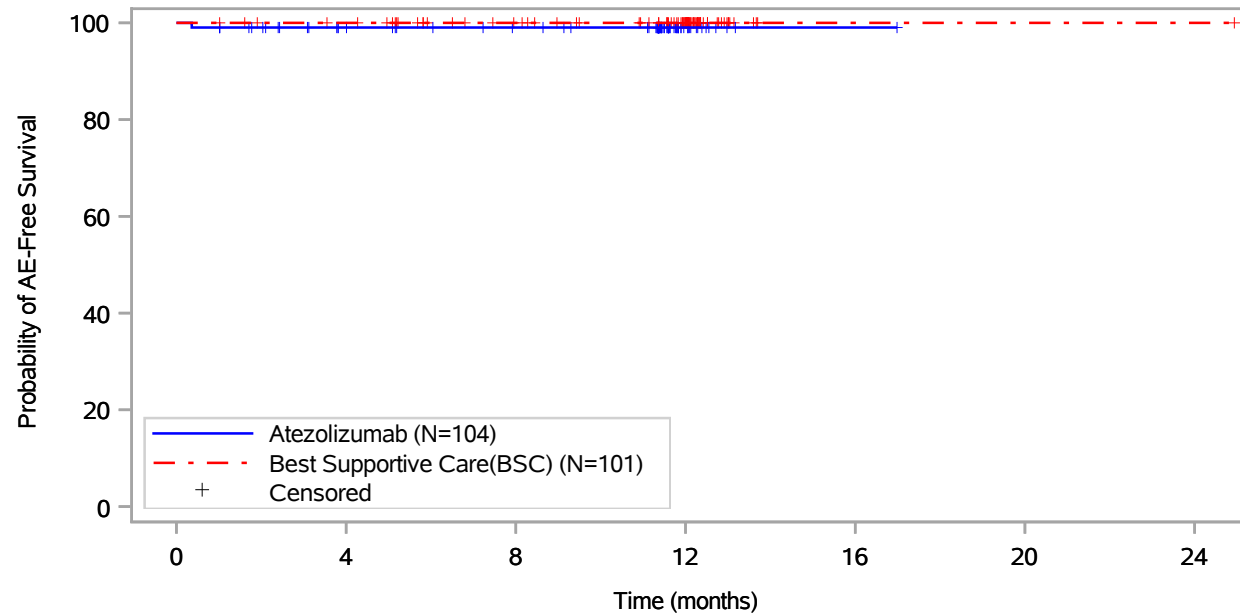
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Encephalitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

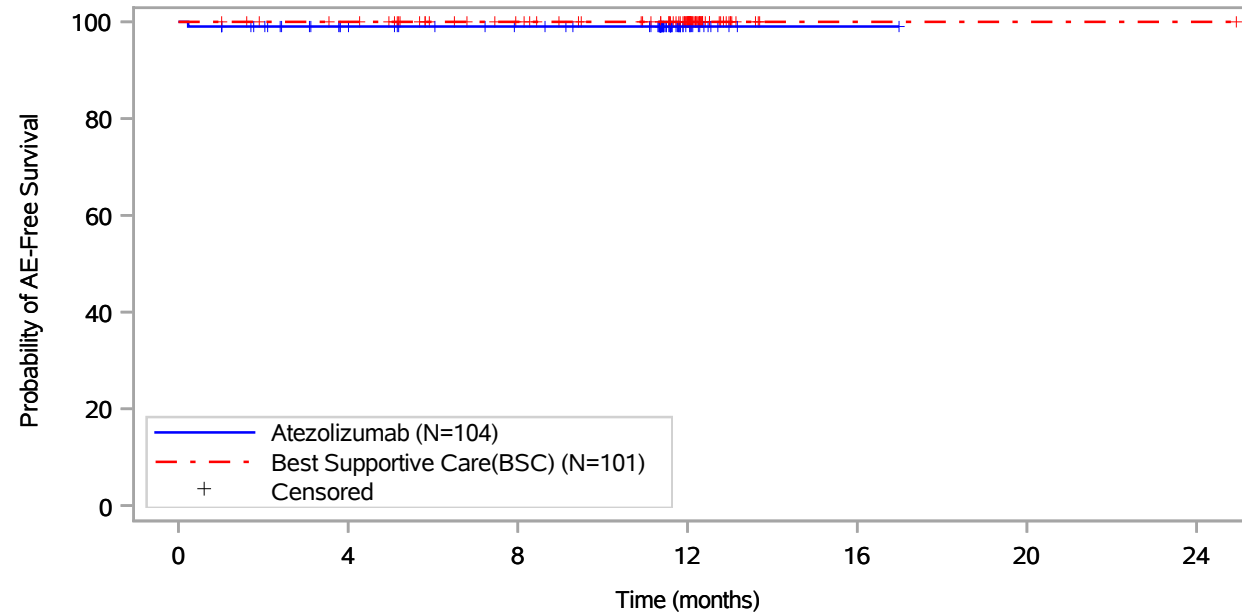
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Fungal pharyngitis



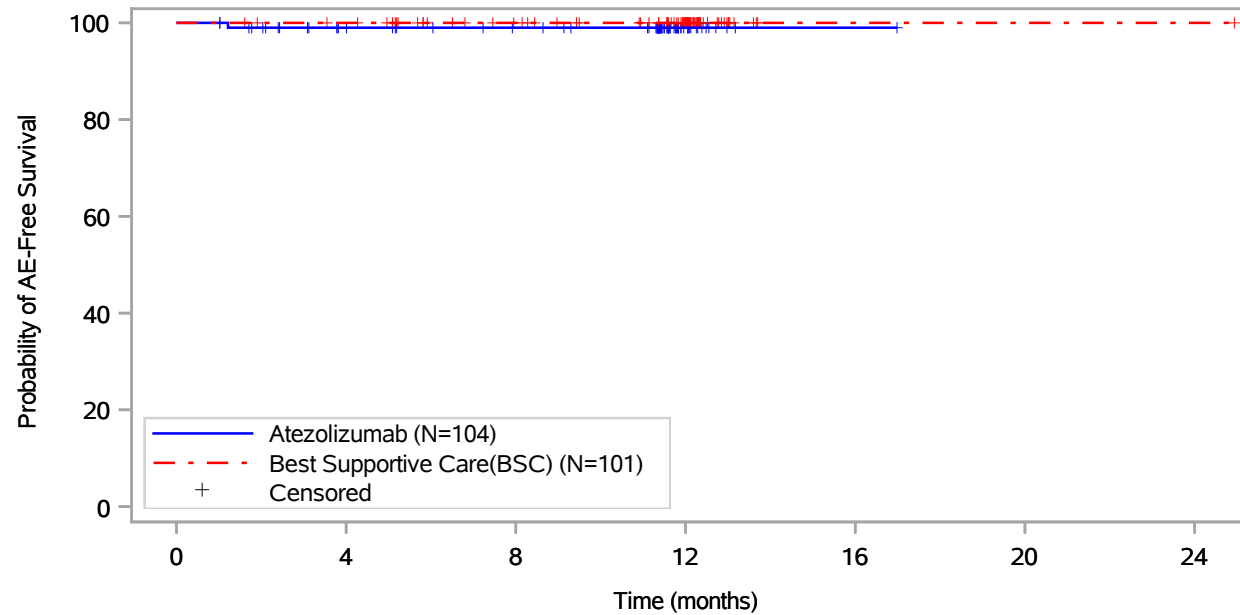
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Furuncle



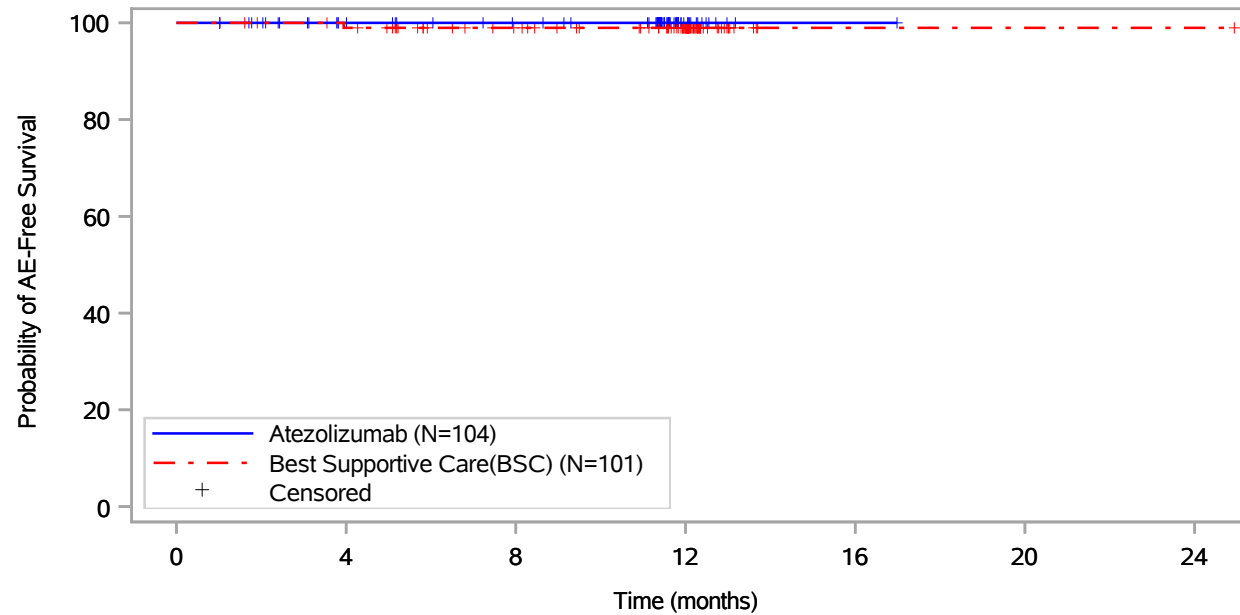
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Gastroenteritis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

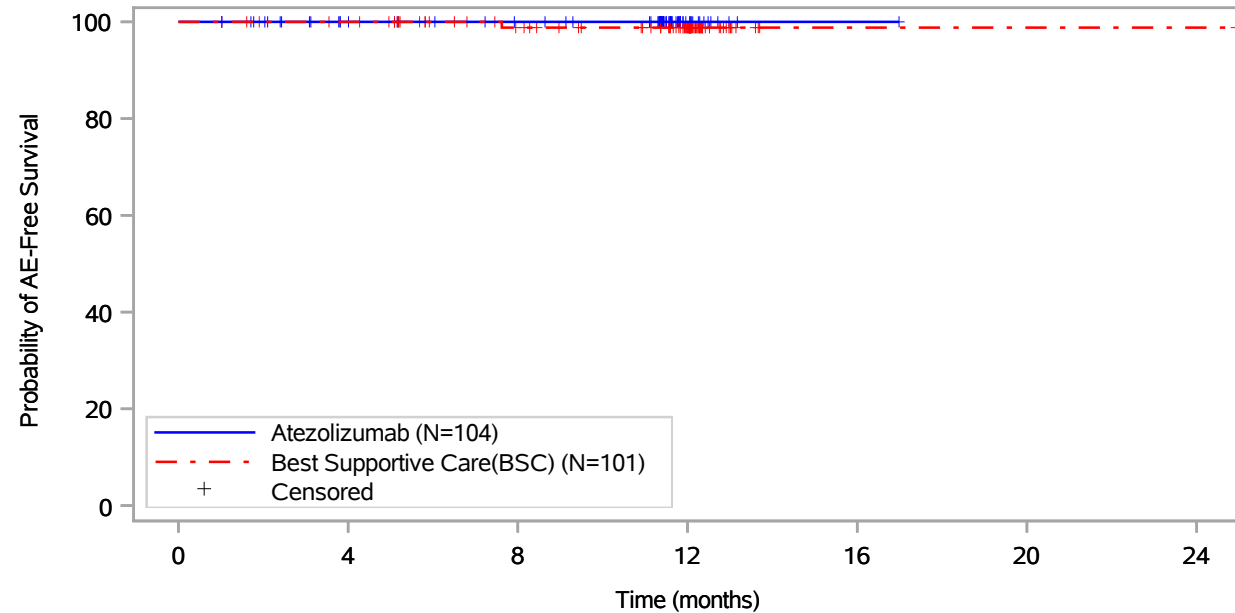
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Gastrointestinal bacterial overgrowth



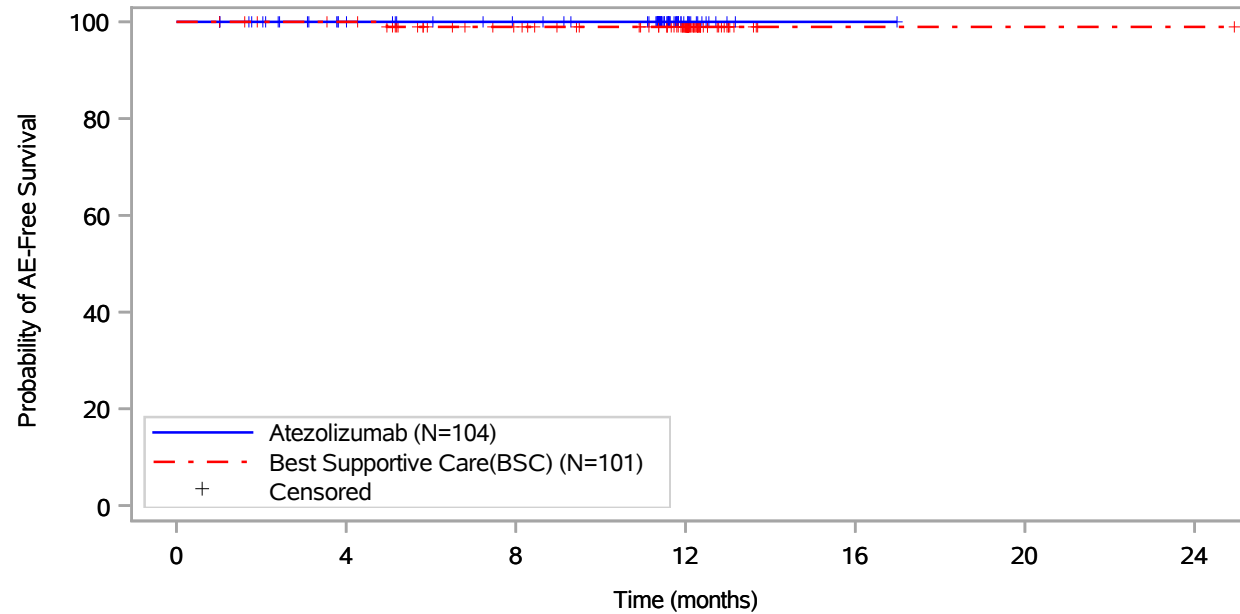
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Herpes zoster



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

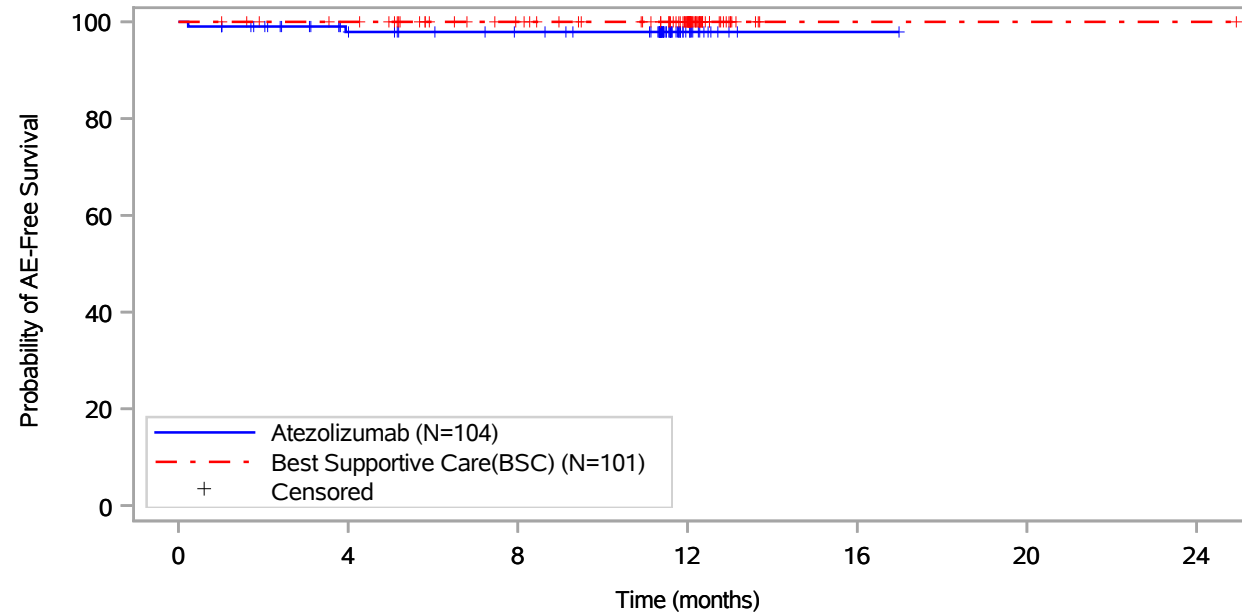
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Infectious pleural effusion



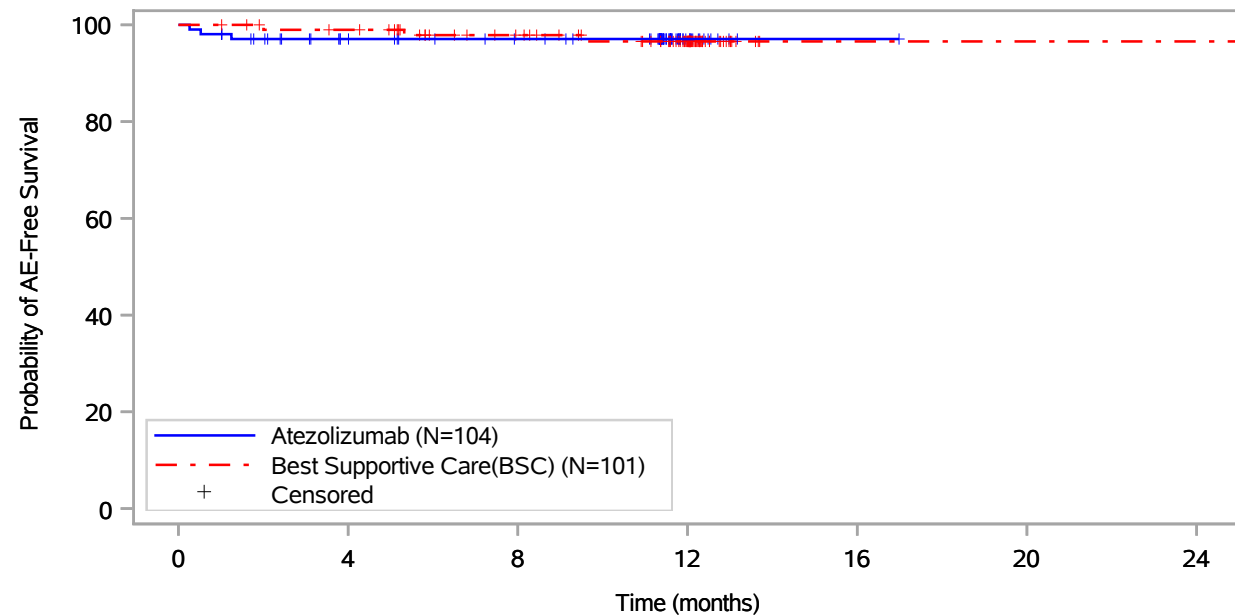
Patients at risk							
Atezolizumab (N=104)	104	87	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Influenza



Patients at risk							
Atezolizumab (N=104)	104	86	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	97	97	97

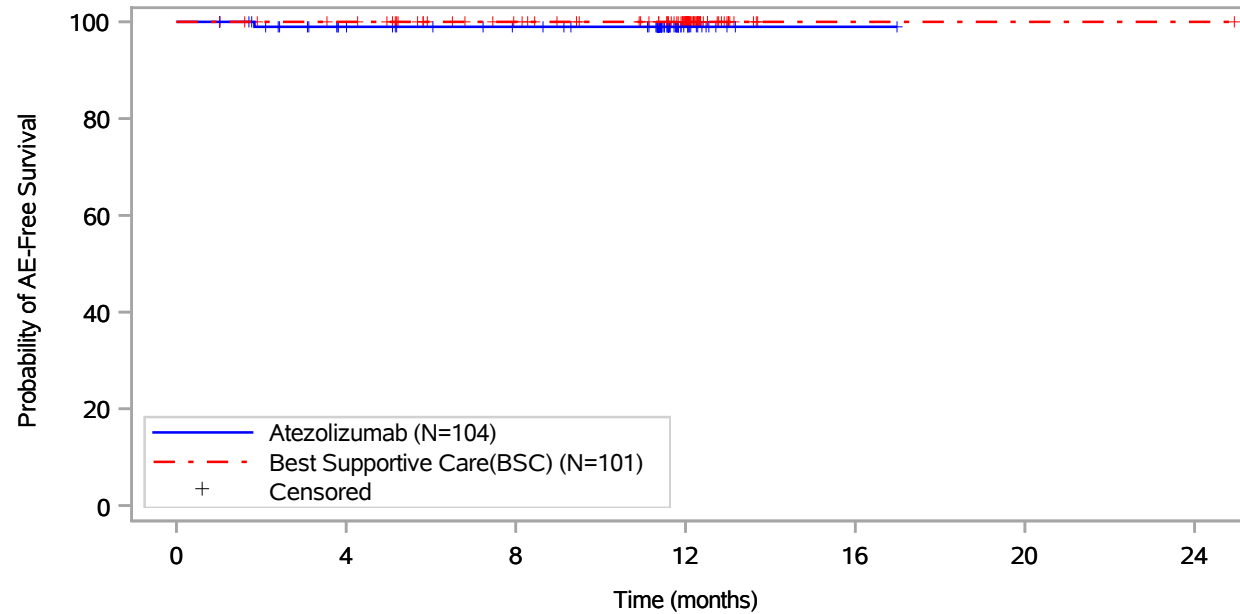
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Kidney infection



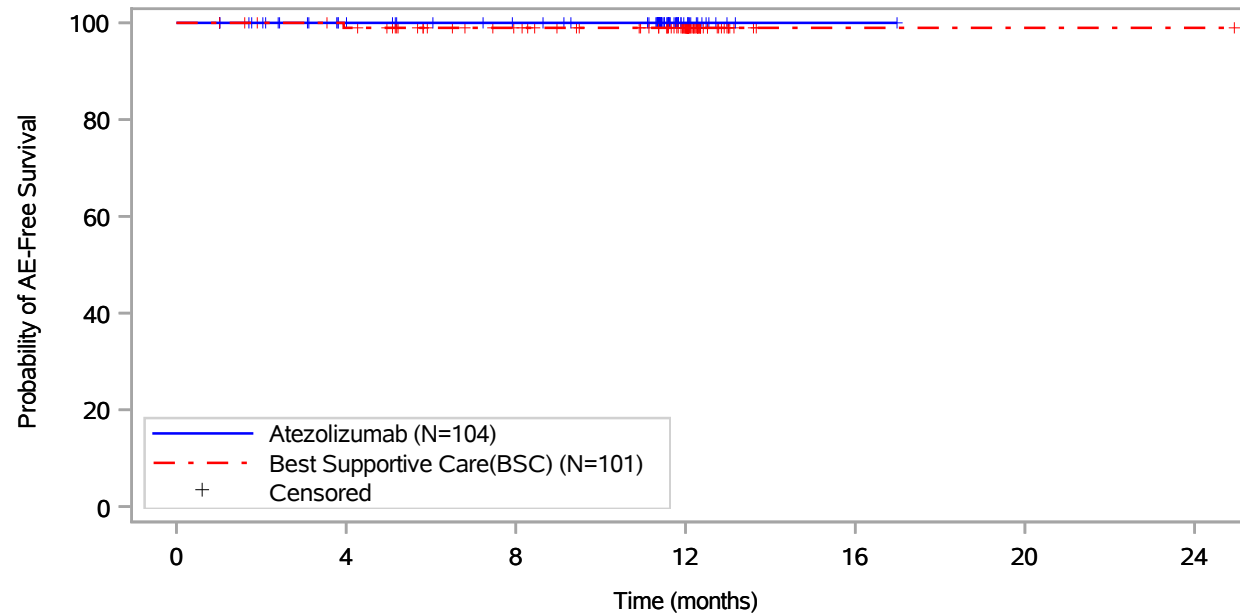
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Laryngitis



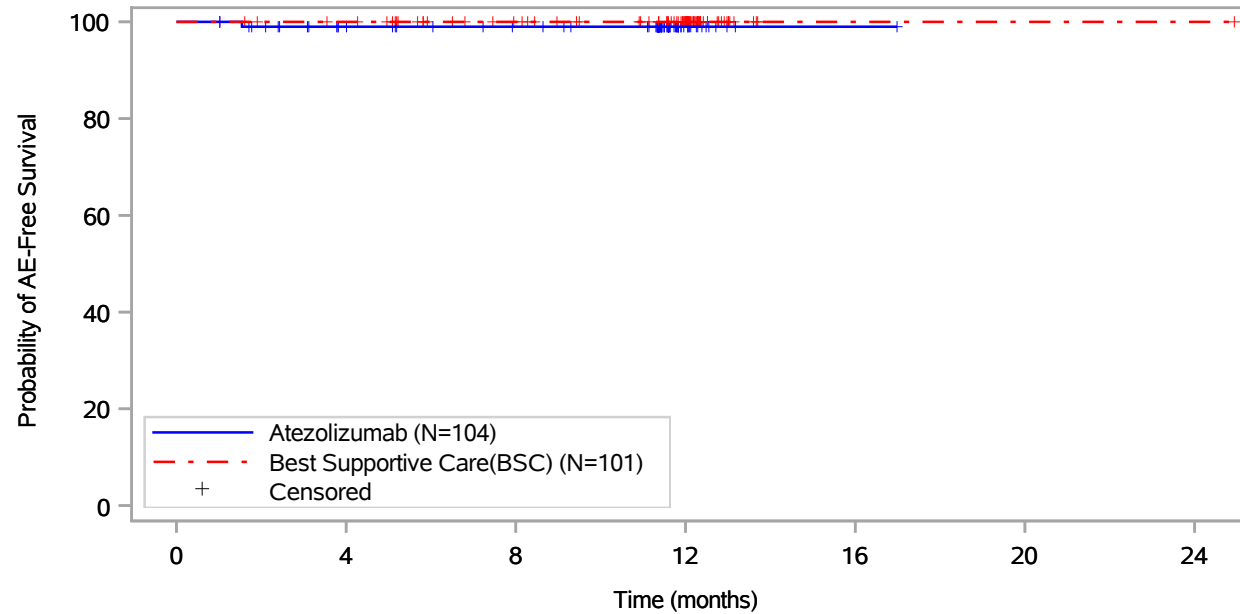
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Meningitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

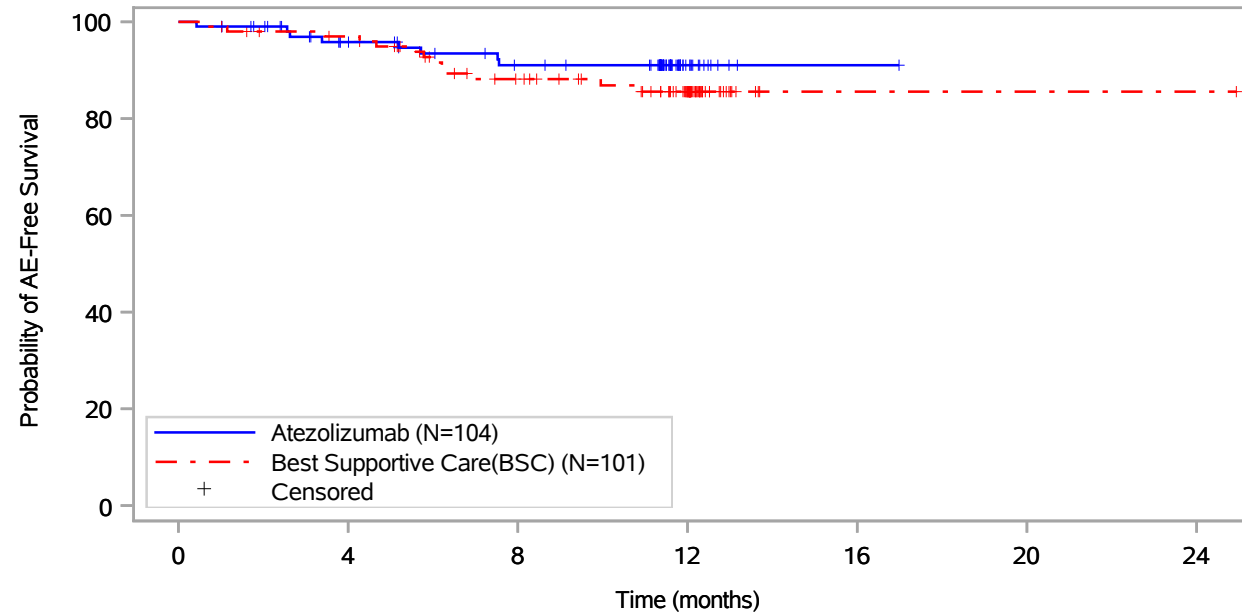
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Nasopharyngitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	85	74	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	74	47	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	83	95	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	16	41	87	87	87	87

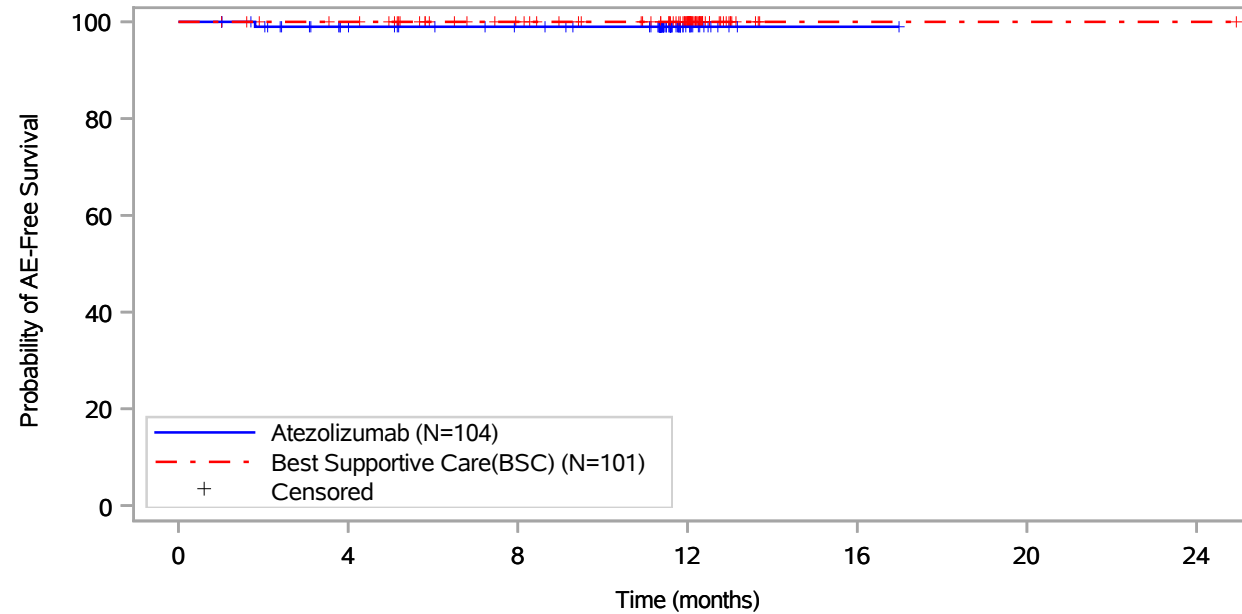
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Oral fungal infection



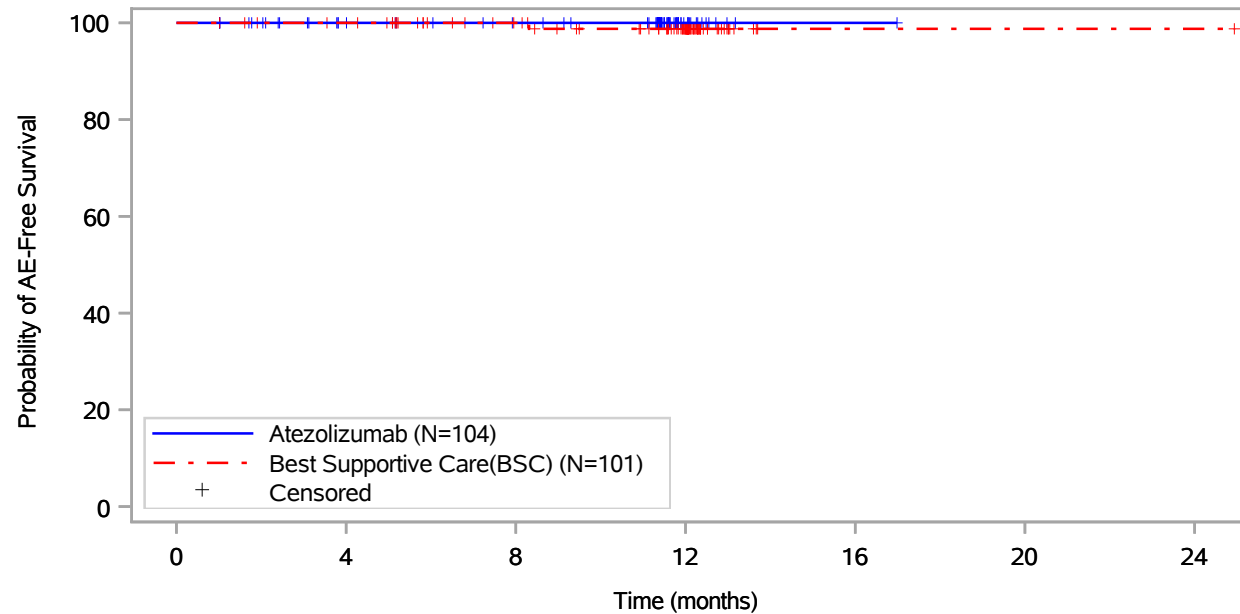
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Oral herpes



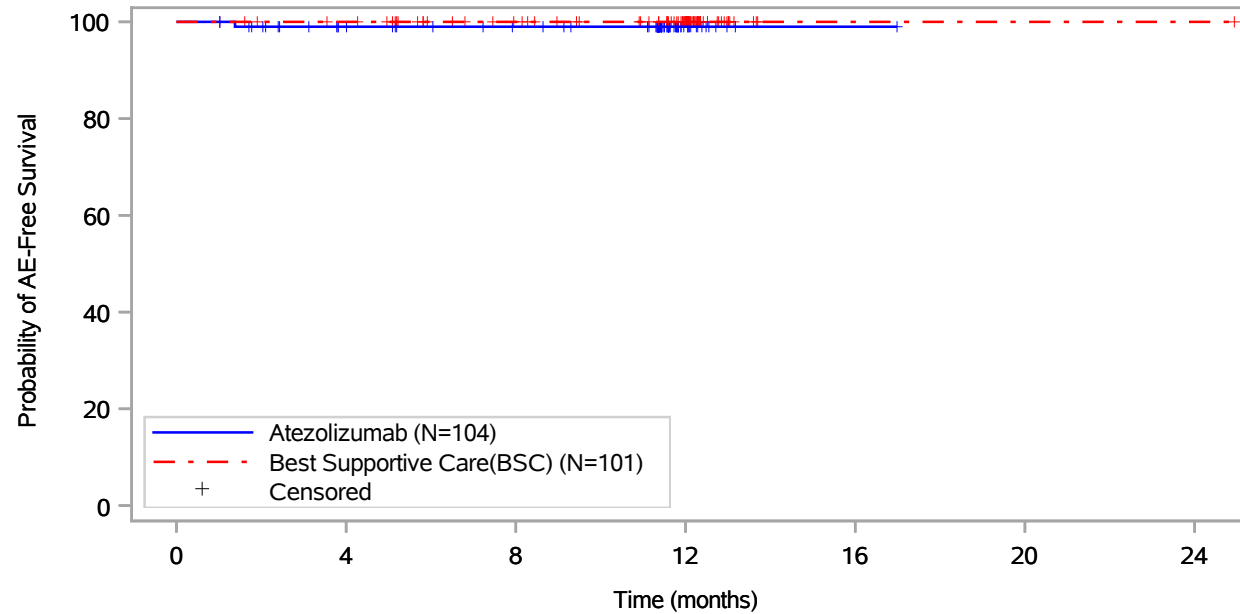
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Otitis externa



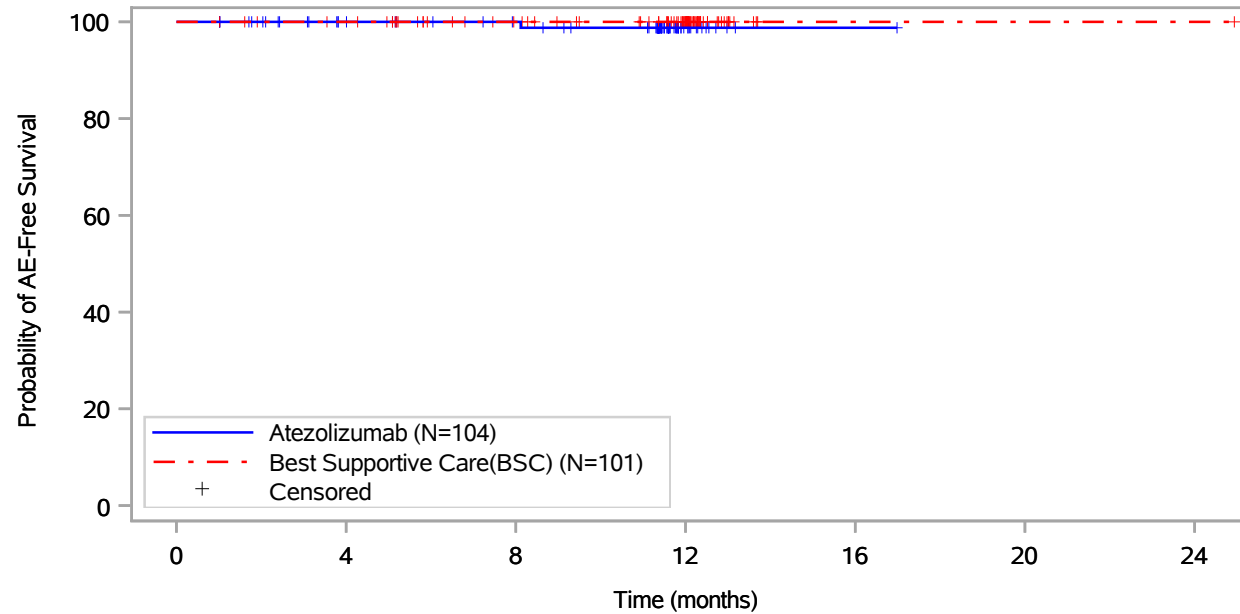
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Otitis media



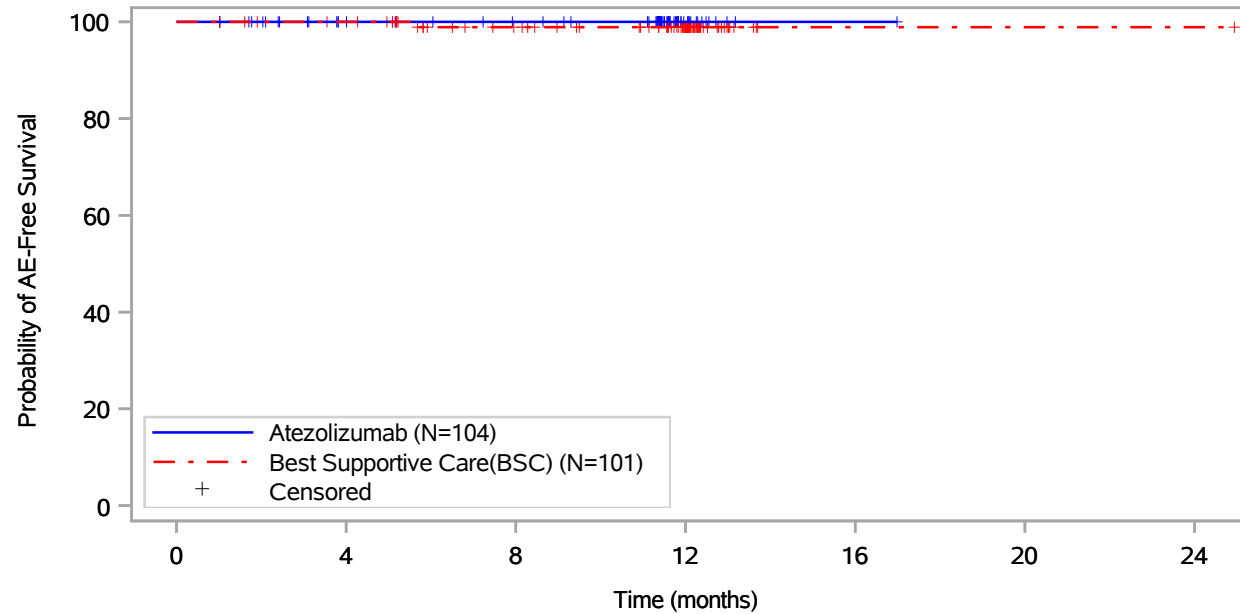
Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Paronychia



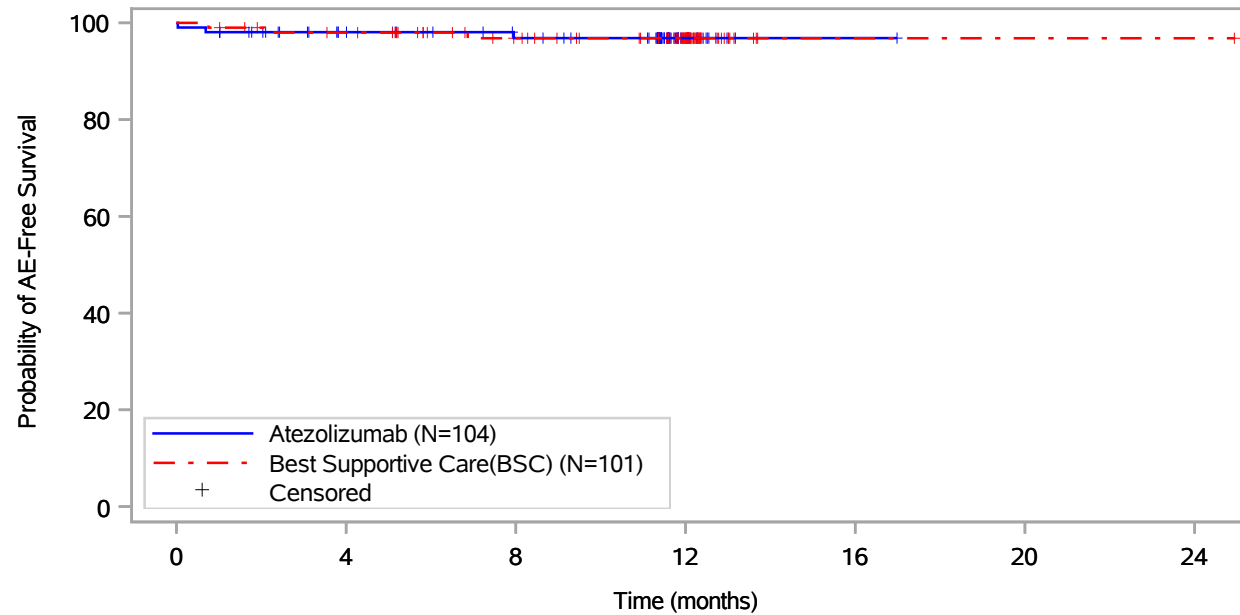
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Pharyngitis



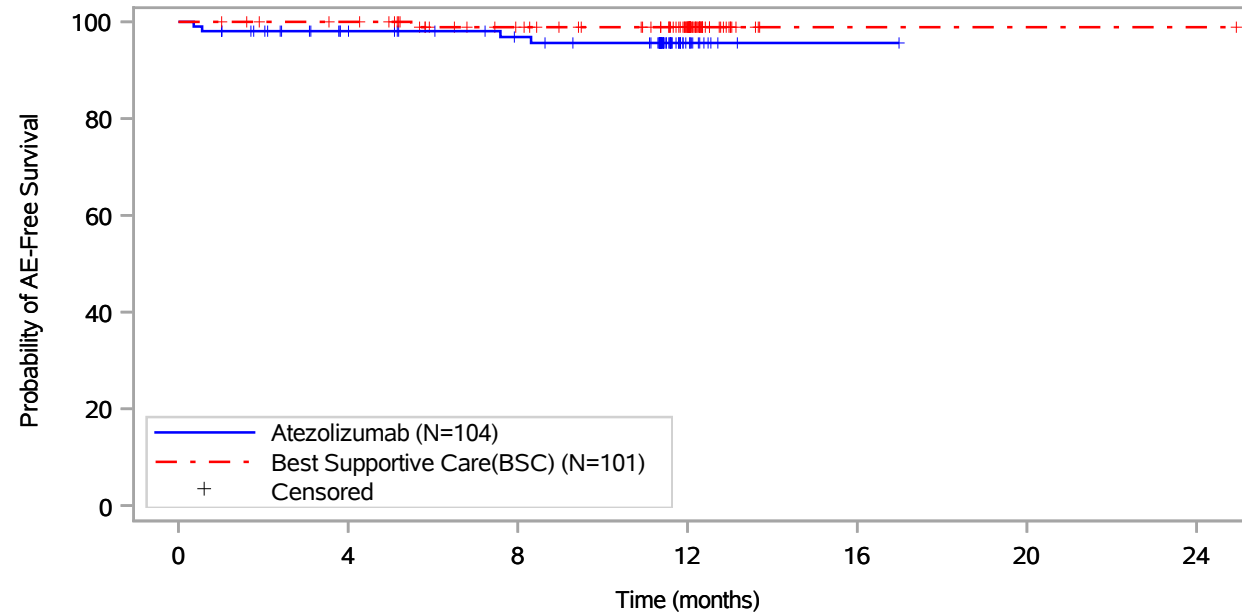
Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	97	97	97

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Pneumonia



Patients at risk							
Atezolizumab (N=104)	104	87	79	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

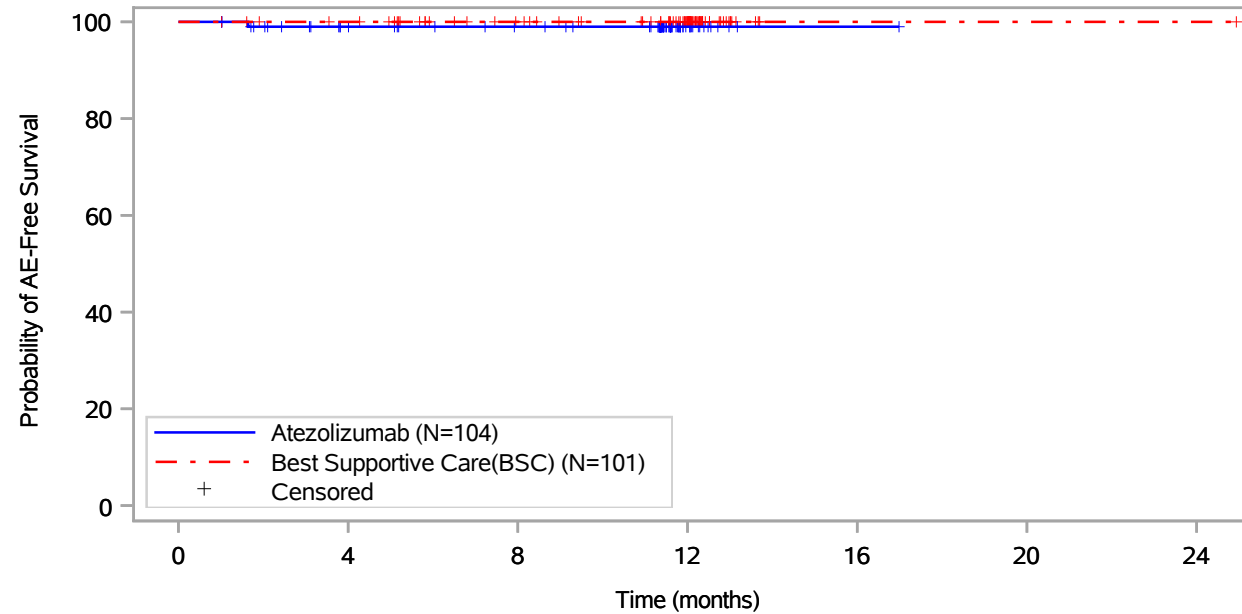
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Pneumonia pneumococcal



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

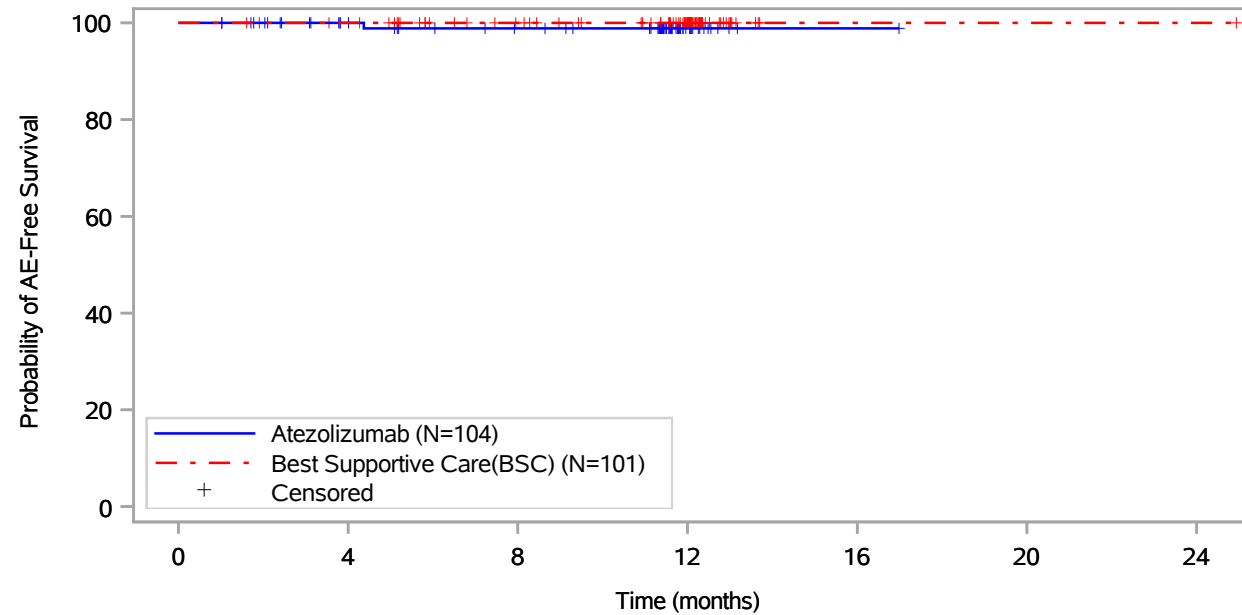
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Prostate infection



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

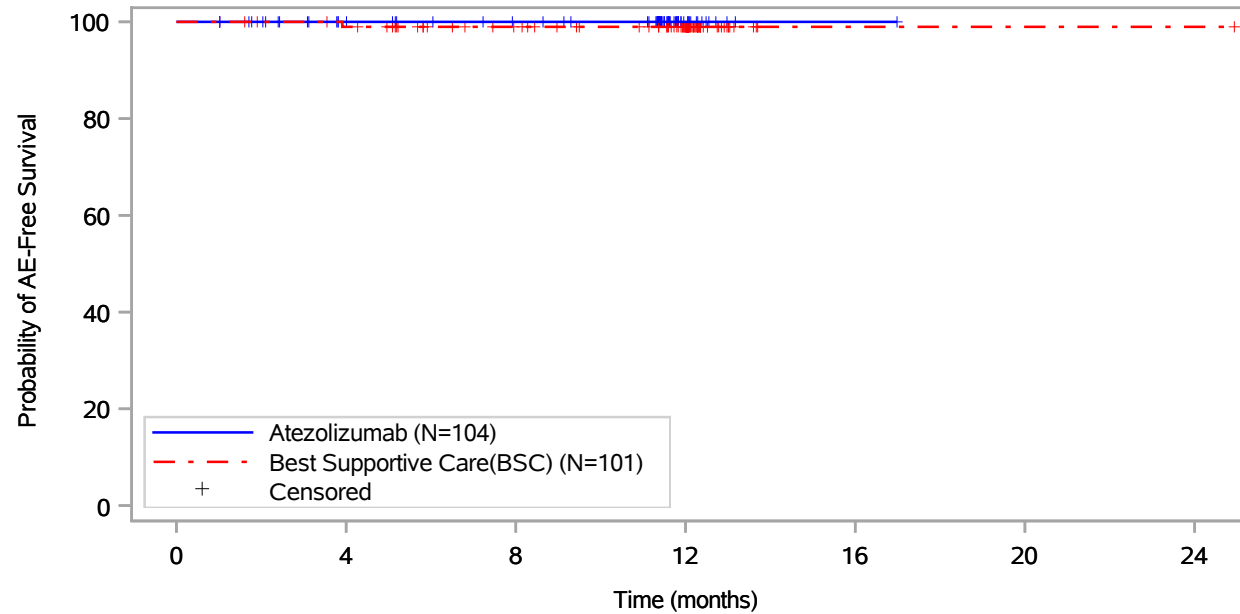
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Pulpitis dental



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

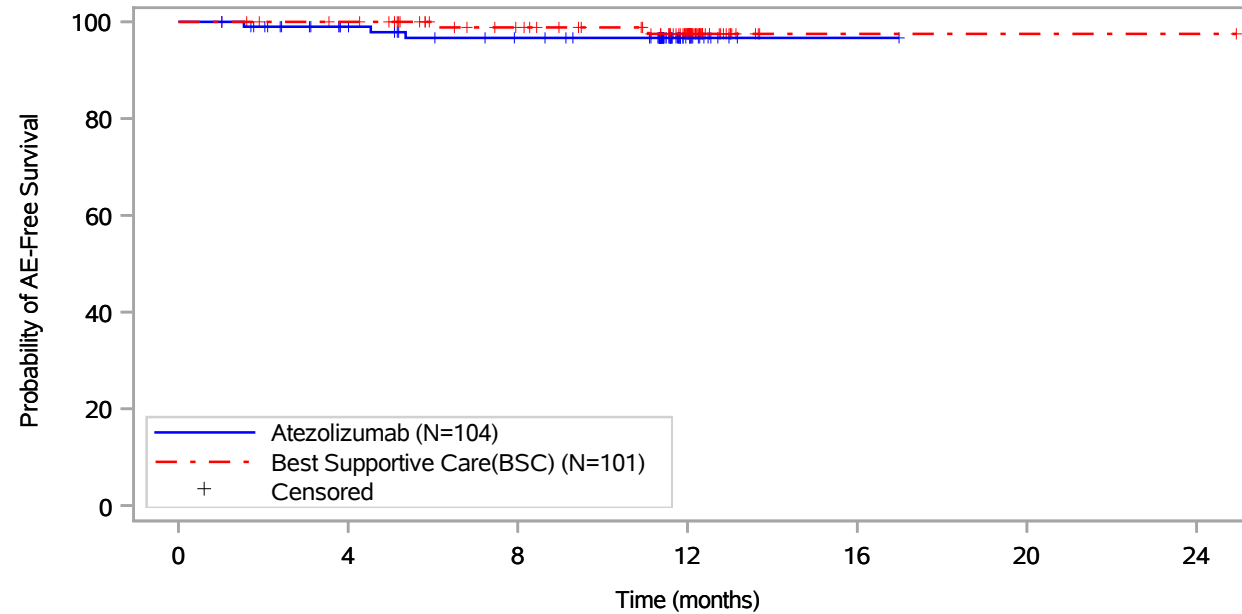
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Respiratory tract infection



Patients at risk							
Atezolizumab (N=104)	104	88	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

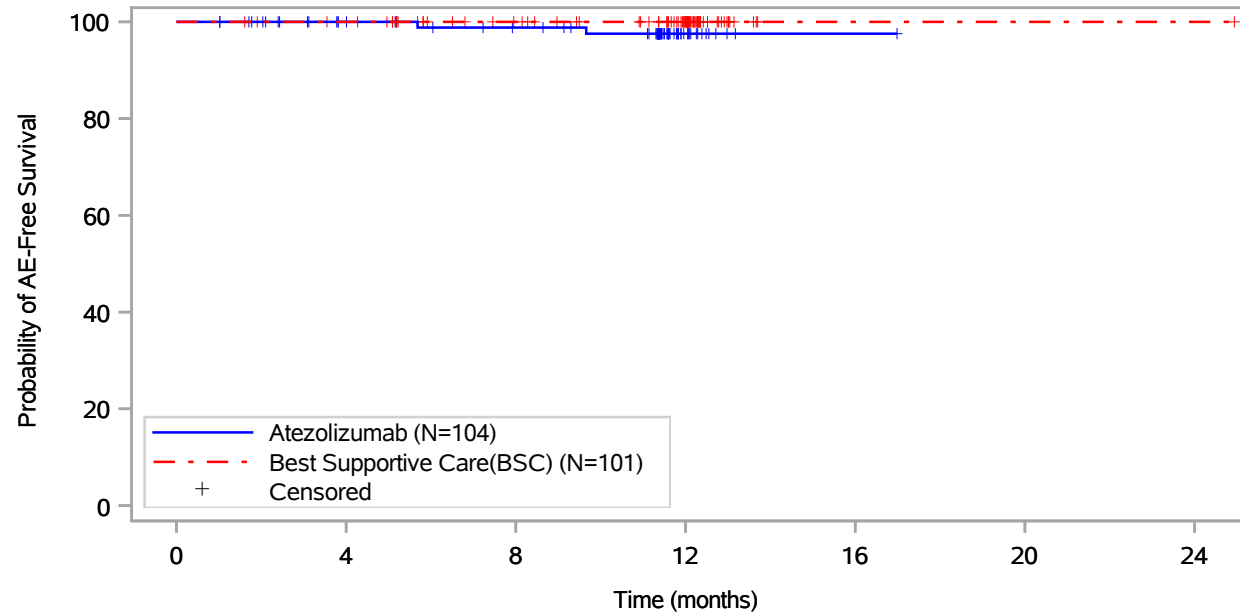
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Respiratory tract infection viral



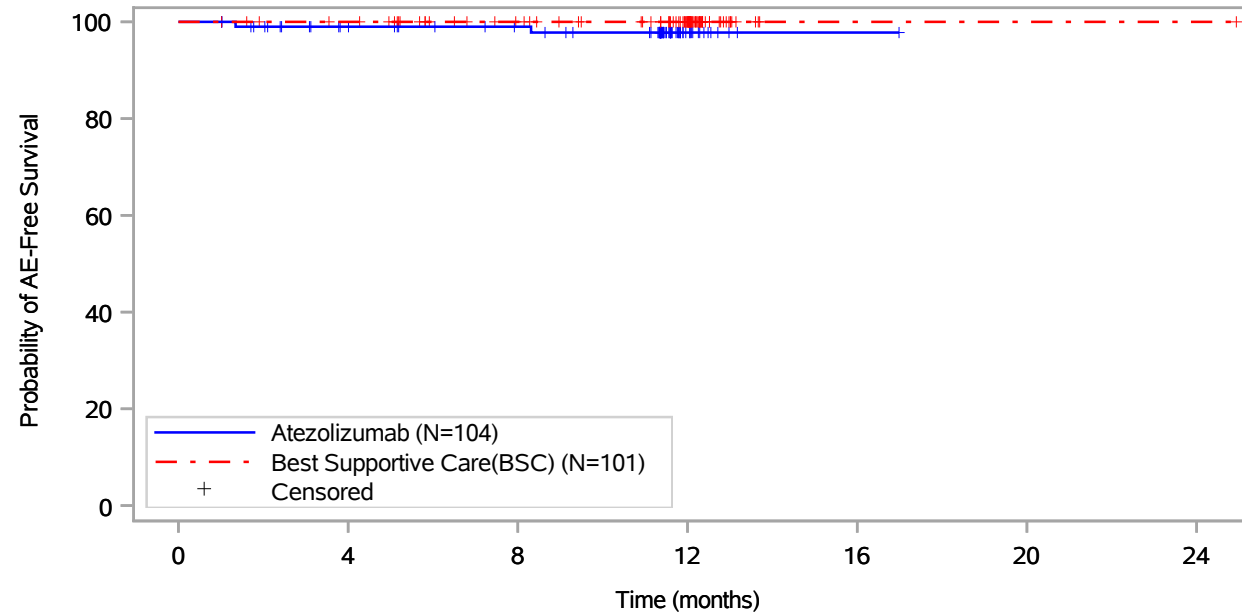
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Rhinitis



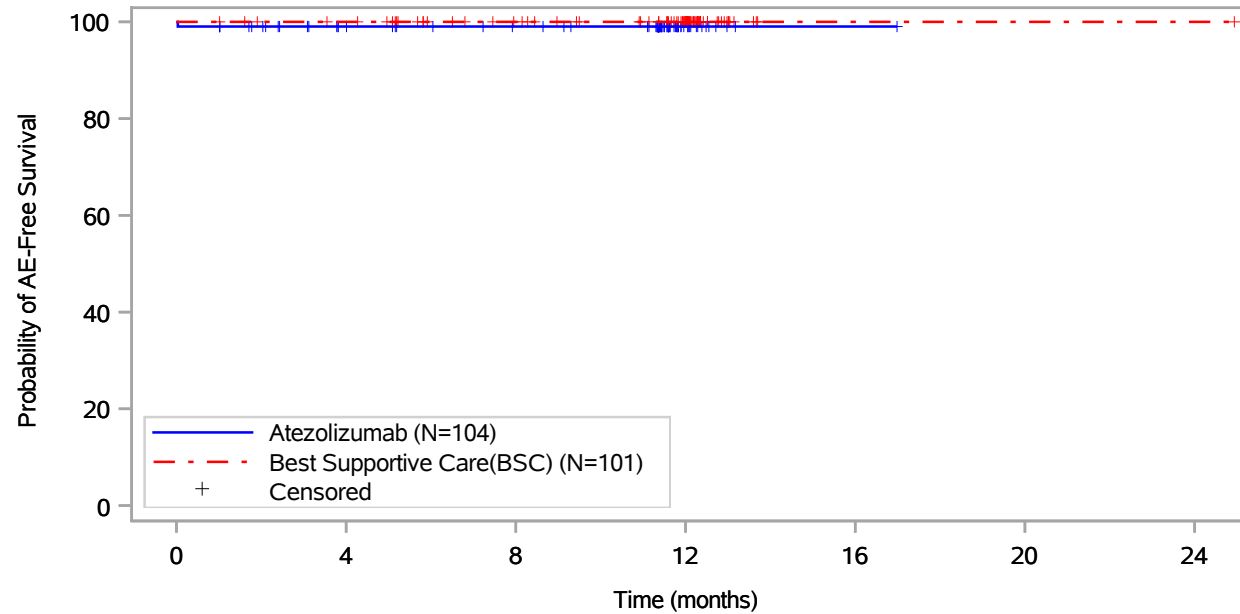
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Sepsis



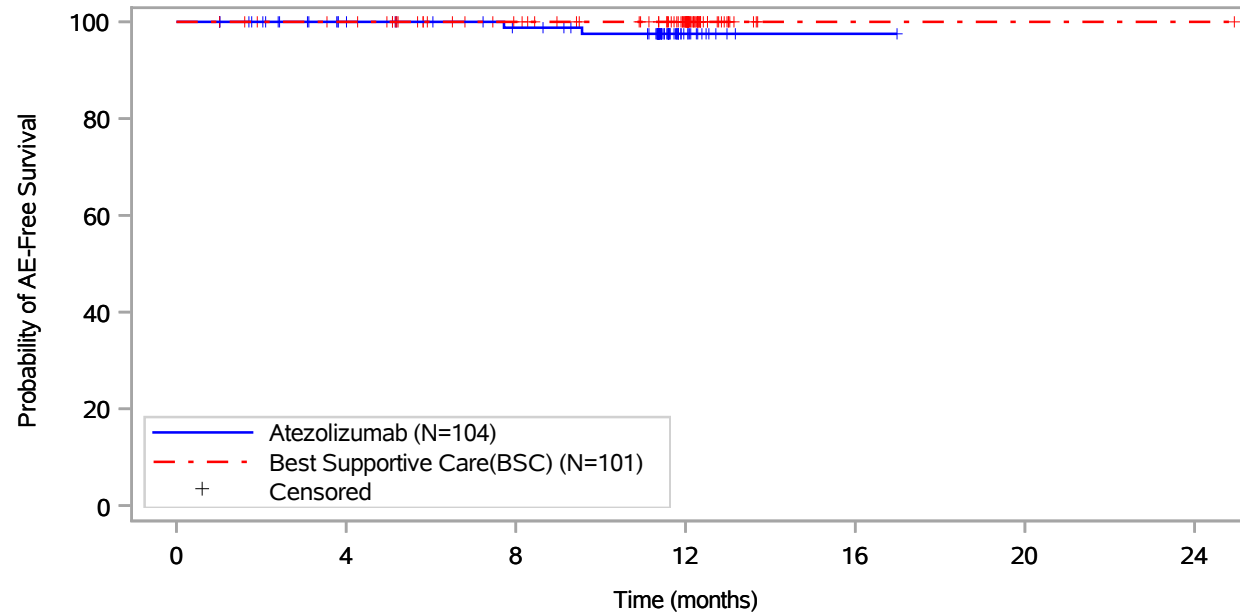
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Sinusitis



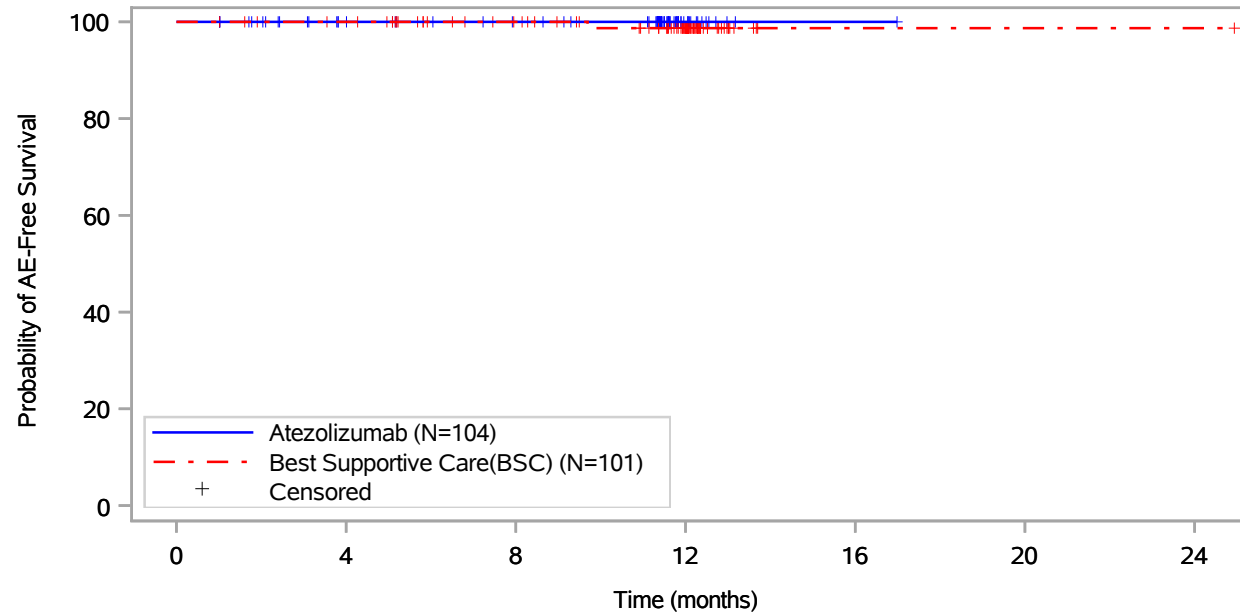
Patients at risk							
Atezolizumab (N=104)	104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Skin infection



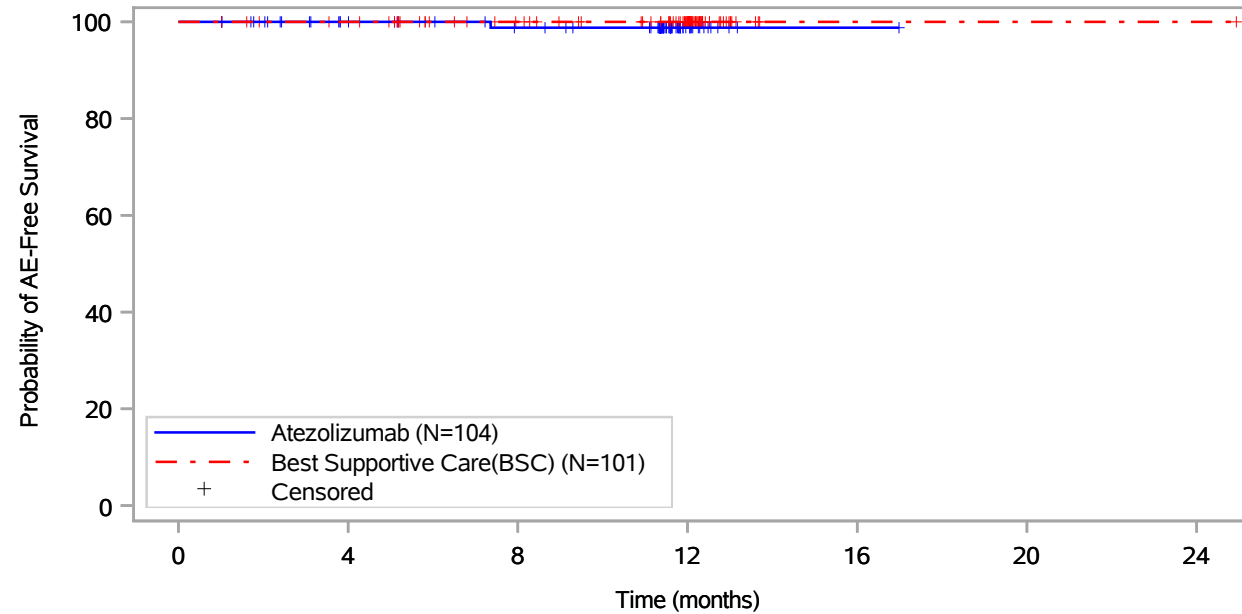
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Tinea infection



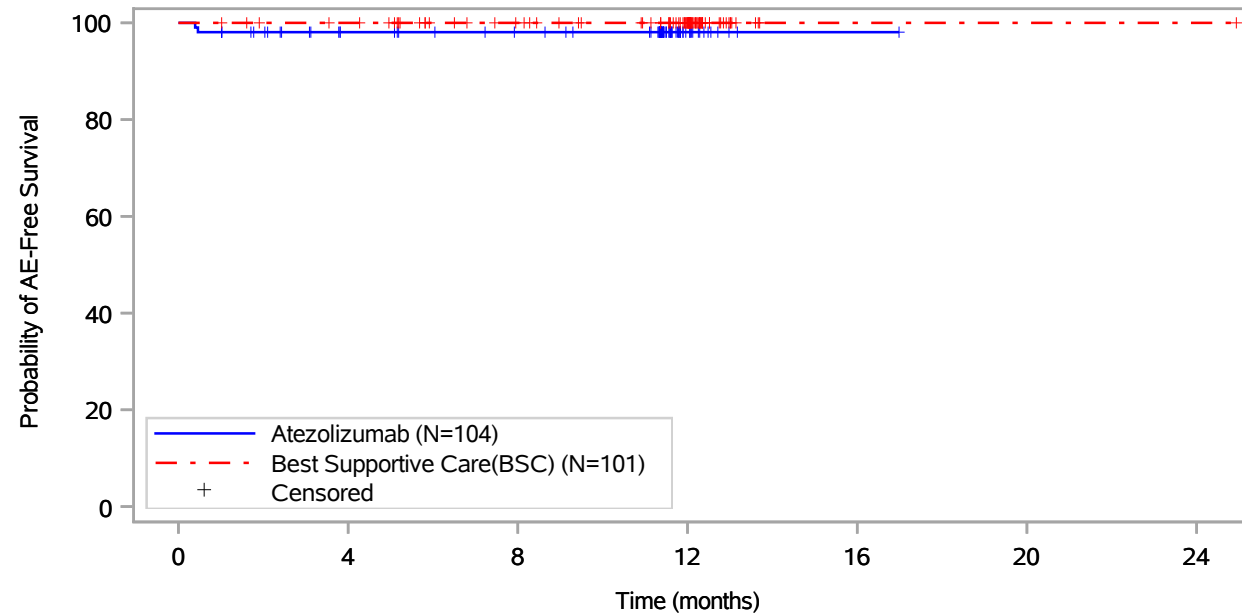
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Tonsillitis



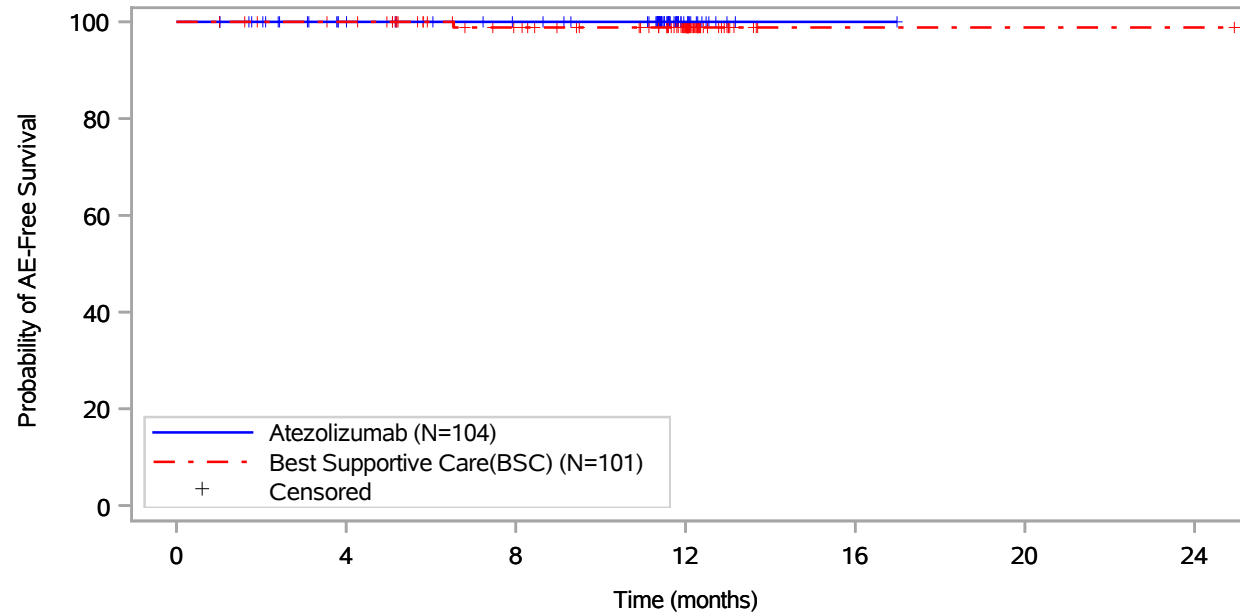
Patients at risk							
Atezolizumab (N=104)	104	87	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Tooth abscess



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

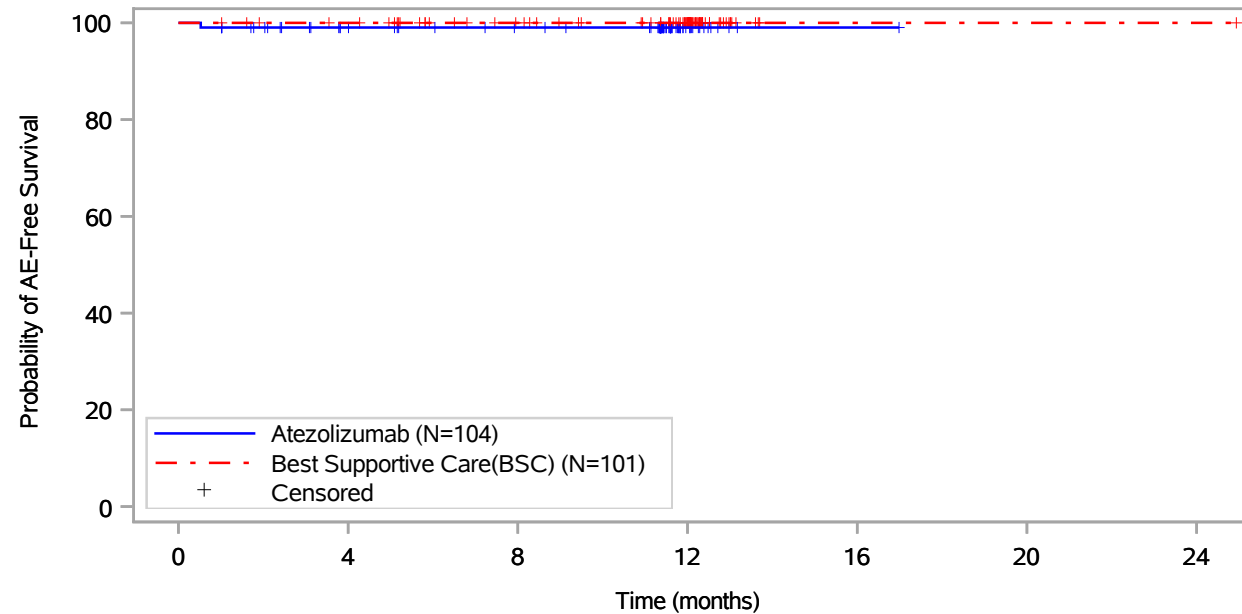
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Tooth infection



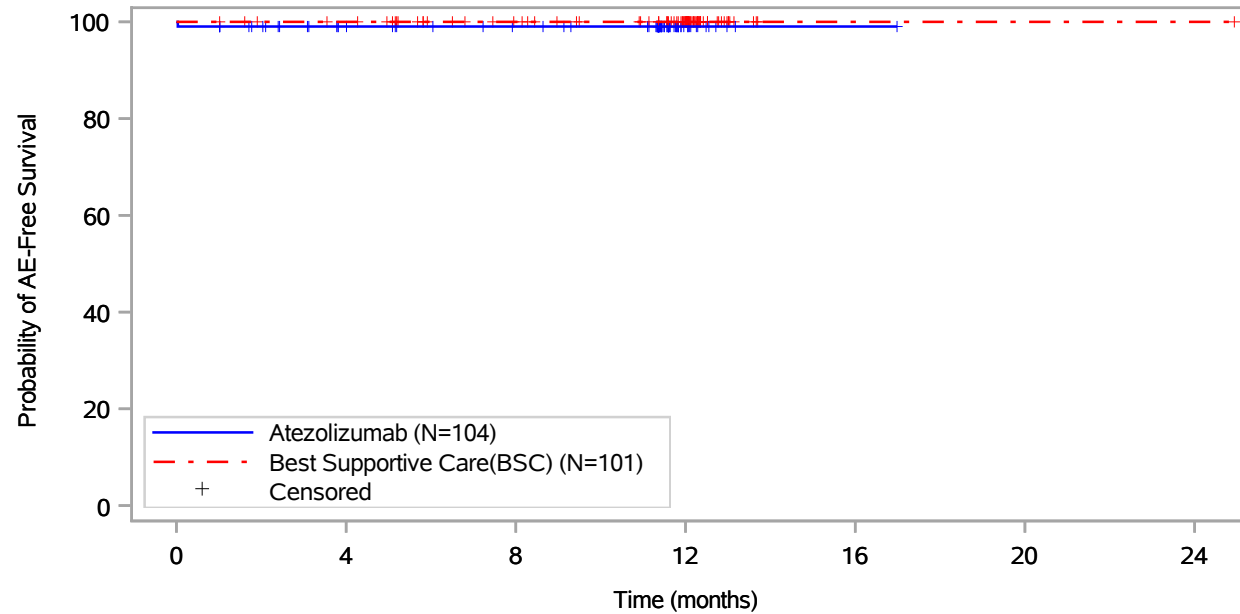
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Infections and infestations, Tracheitis



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

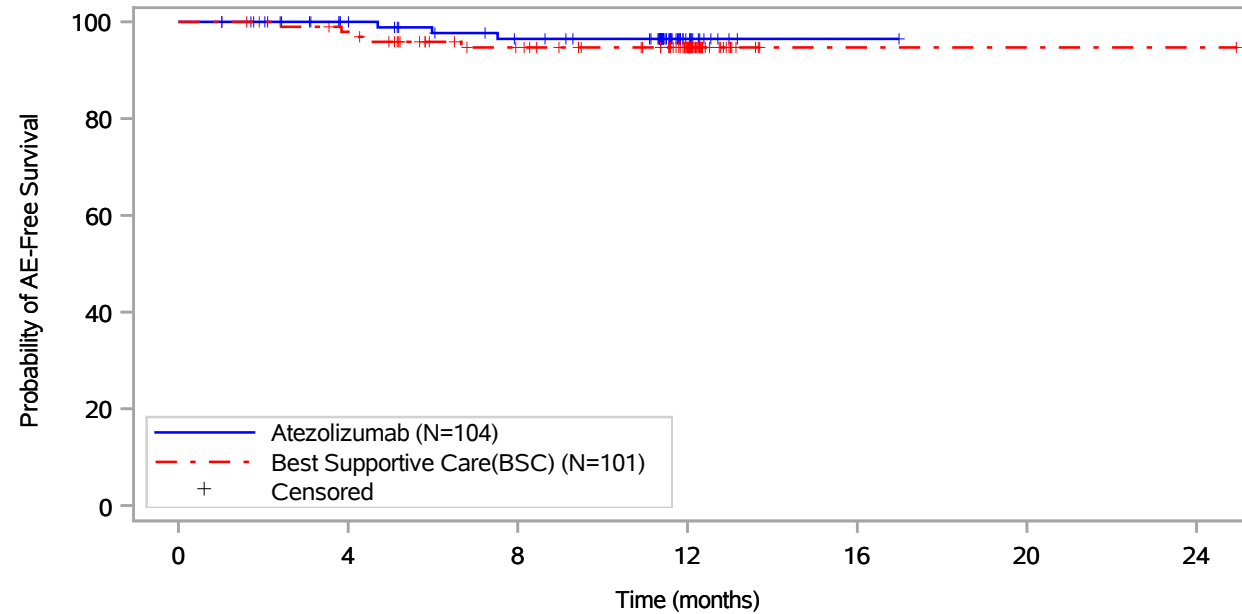
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Upper respiratory tract infection



Patients at risk							
Atezolizumab (N=104)	104	89	79	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	79	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	43	95	95	95

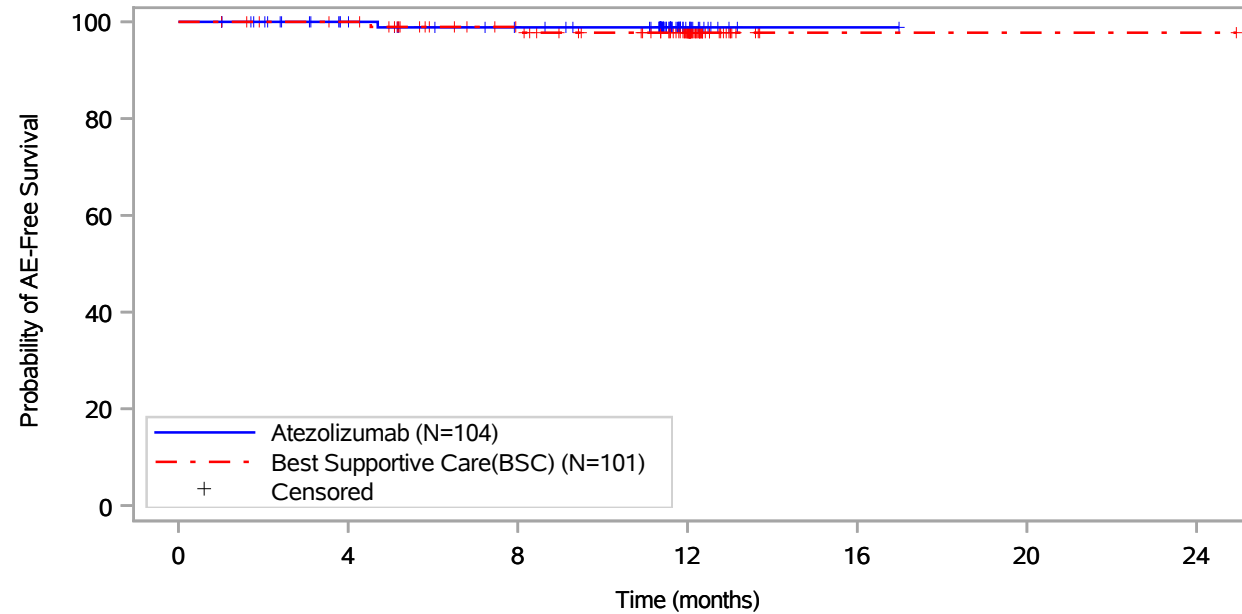
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Urinary tract infection



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	98	98	98

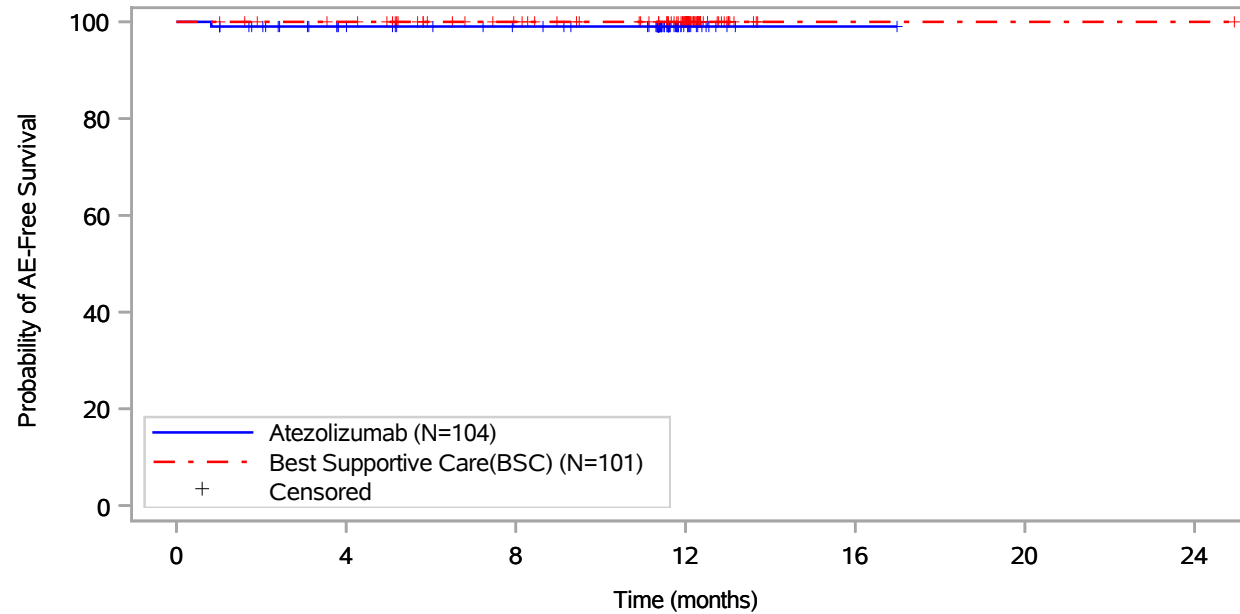
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Vaginal infection



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

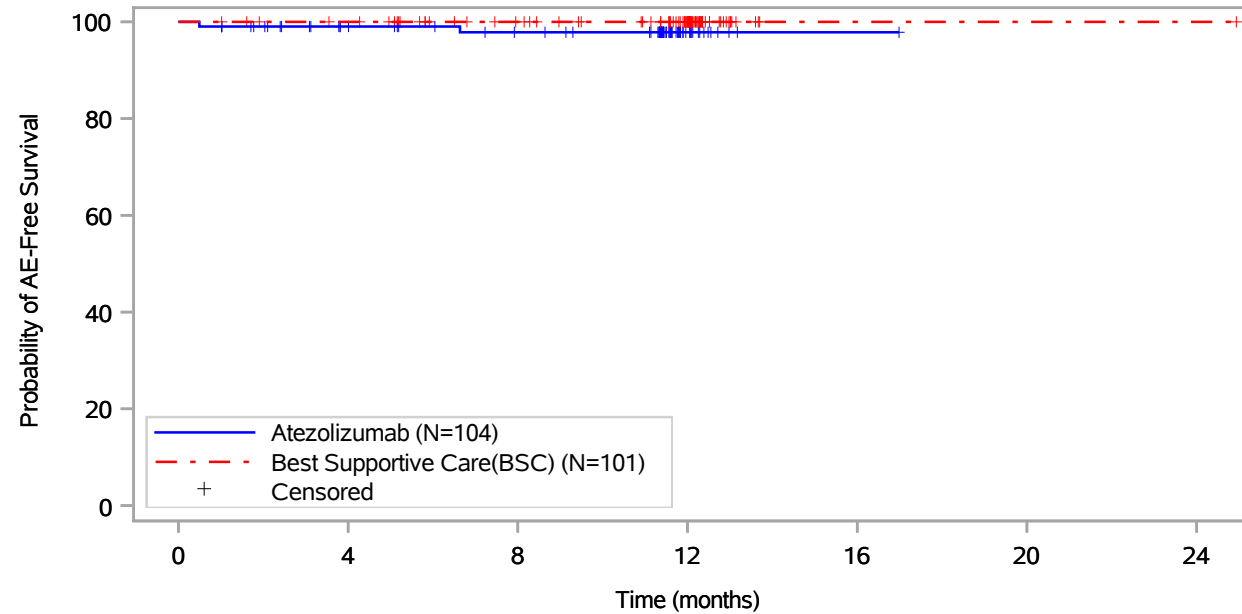
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Viral infection



Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

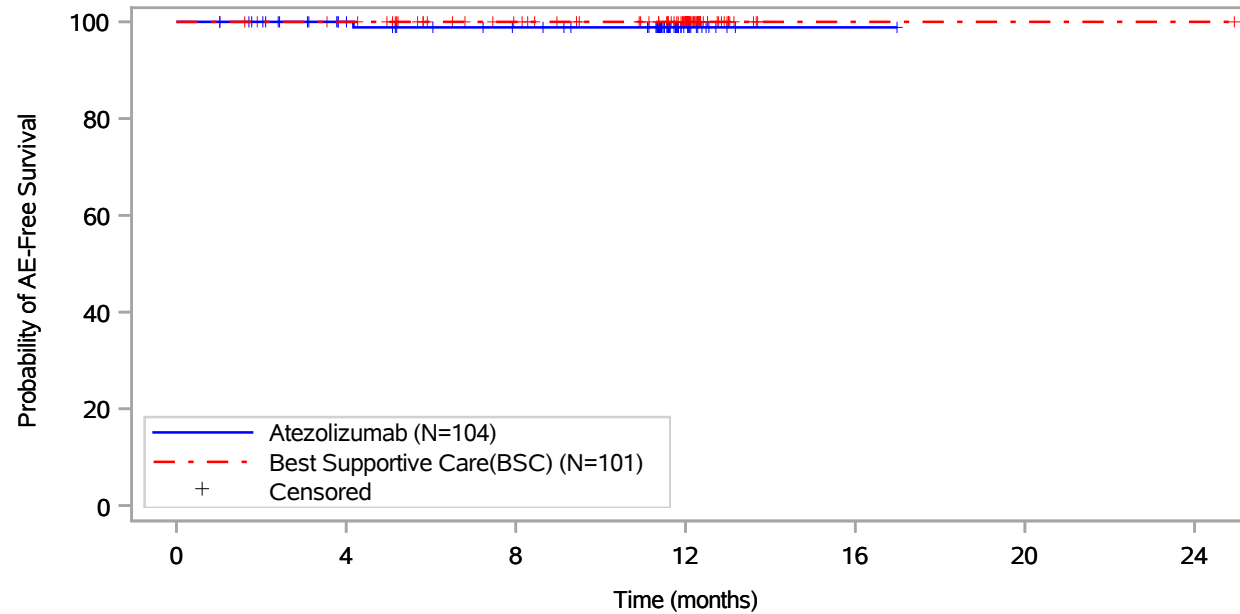
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Viral upper respiratory tract infection



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

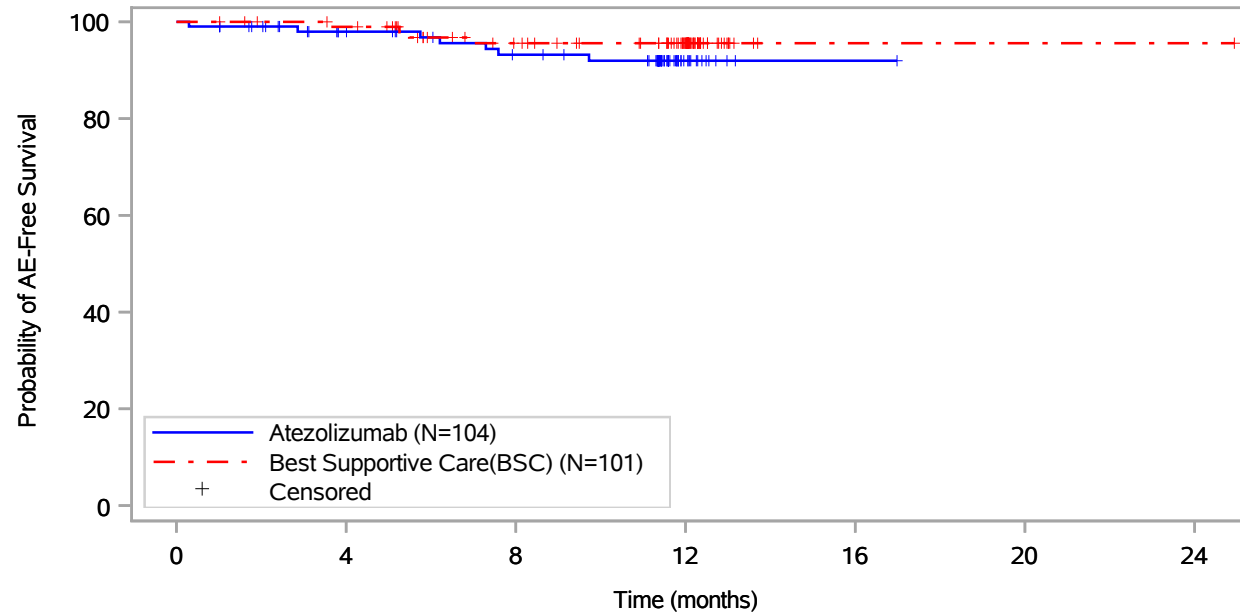
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, All



Patients at risk							
Atezolizumab (N=104)	104	87	77	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	79	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	84	96	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	96	96	96

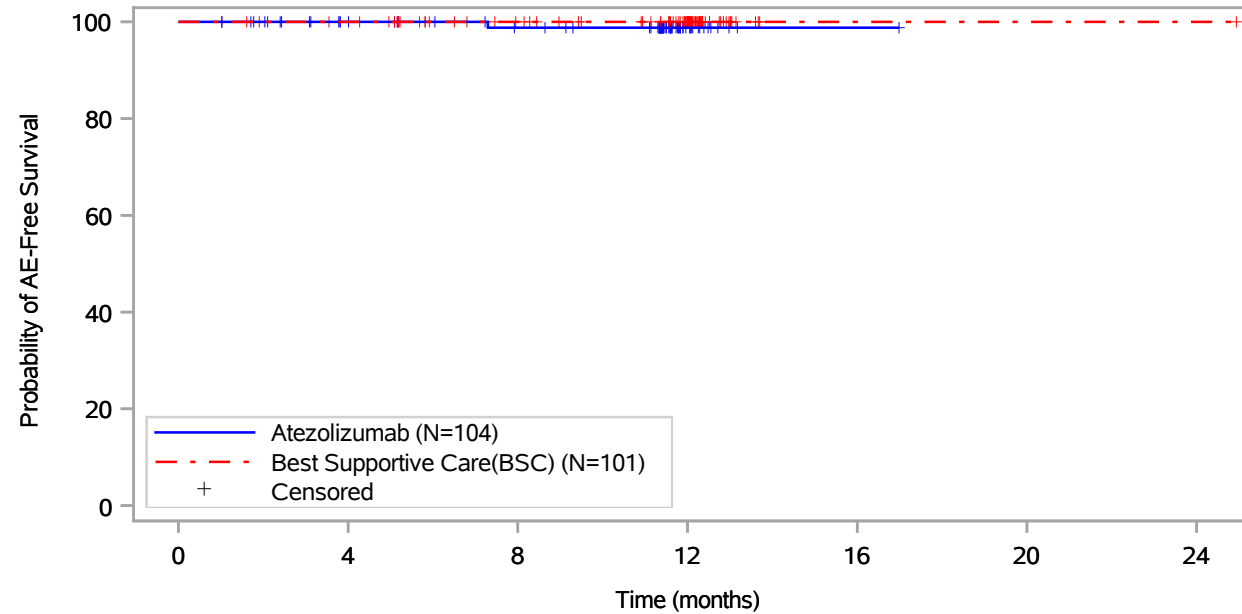
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Contusion



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

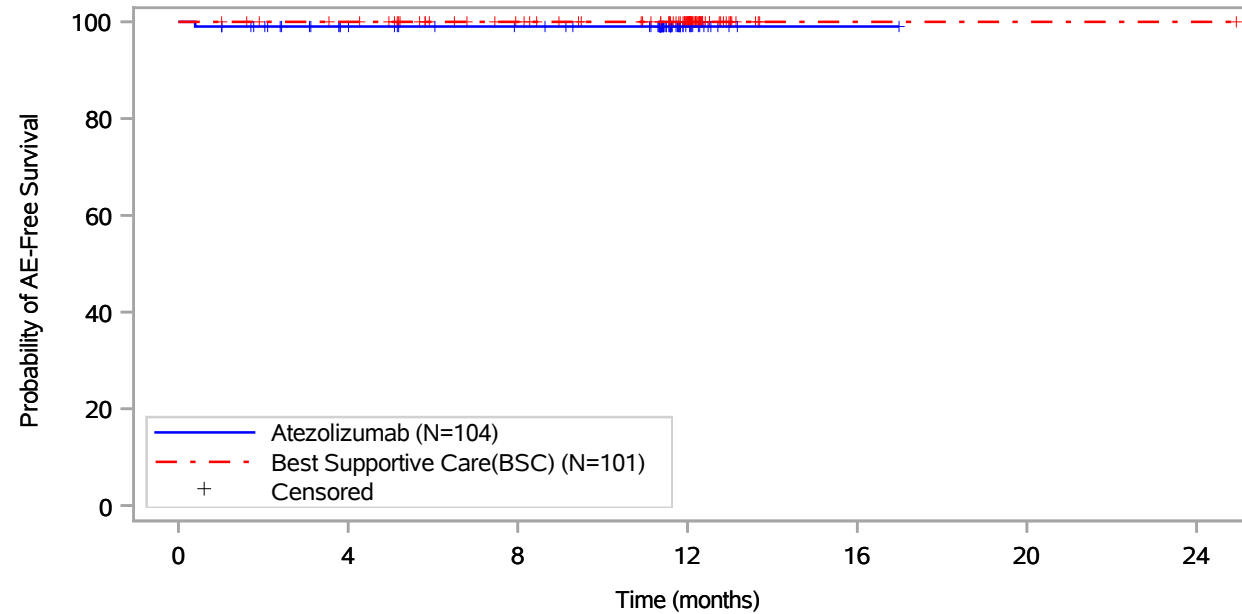
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Eye contusion



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

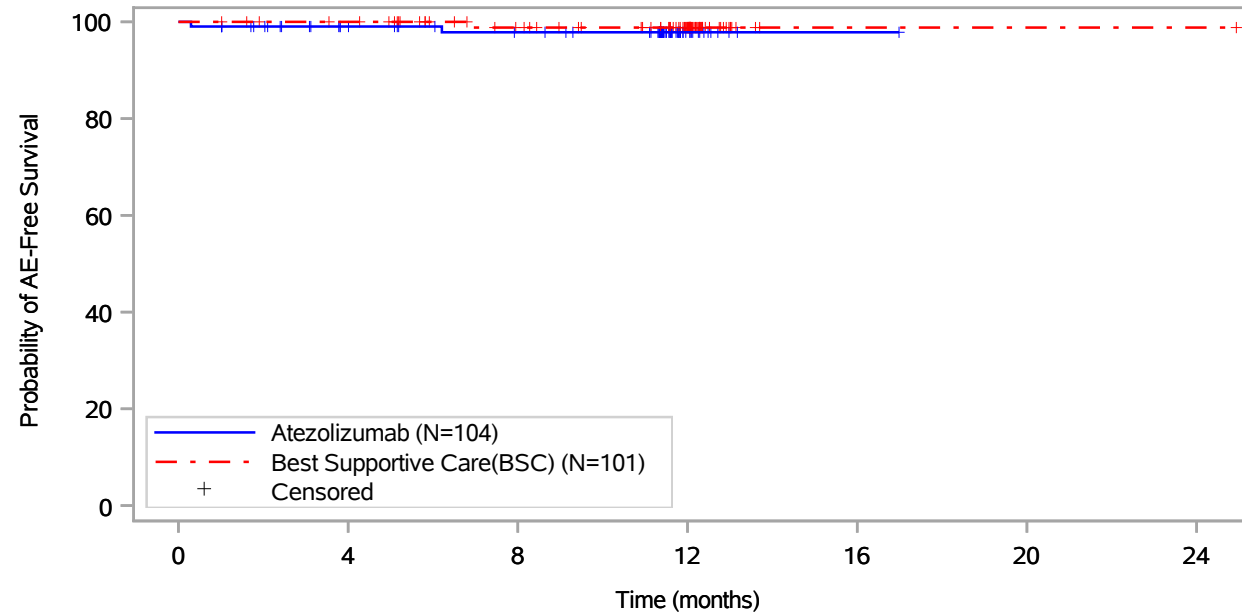
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Fall



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

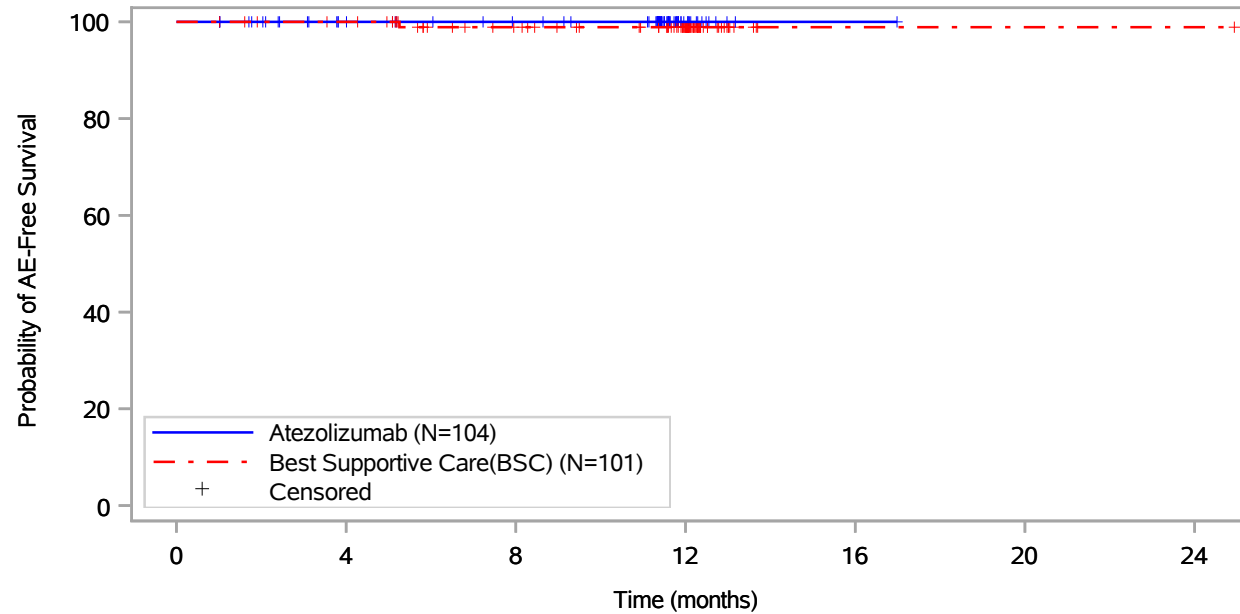
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Fracture



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

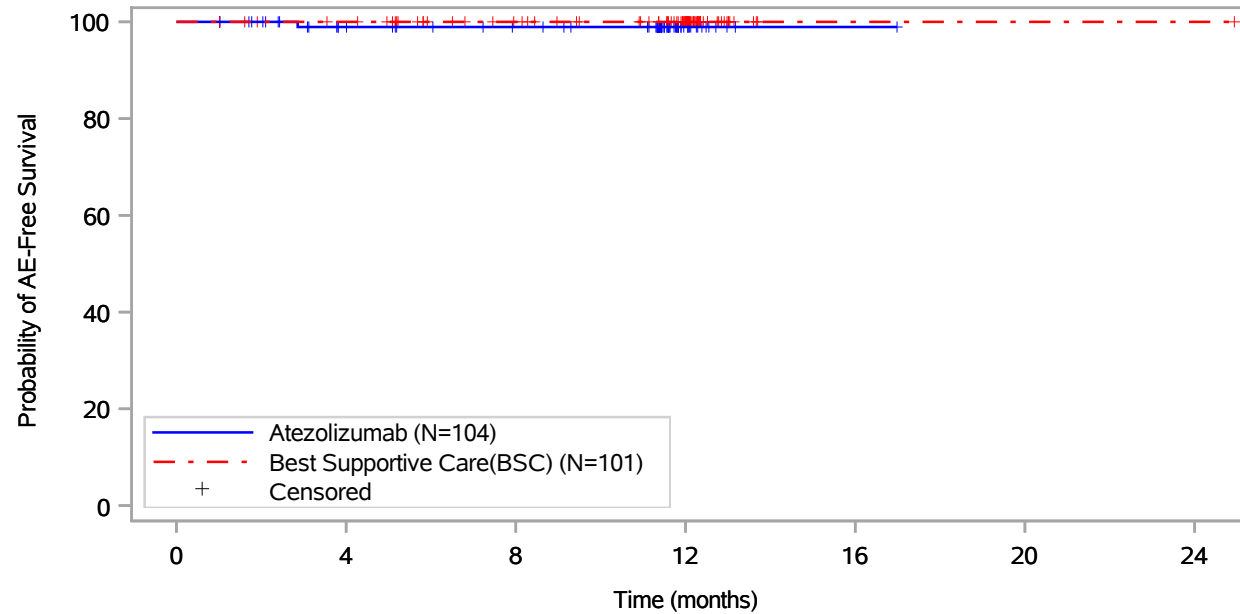
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Joint dislocation



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

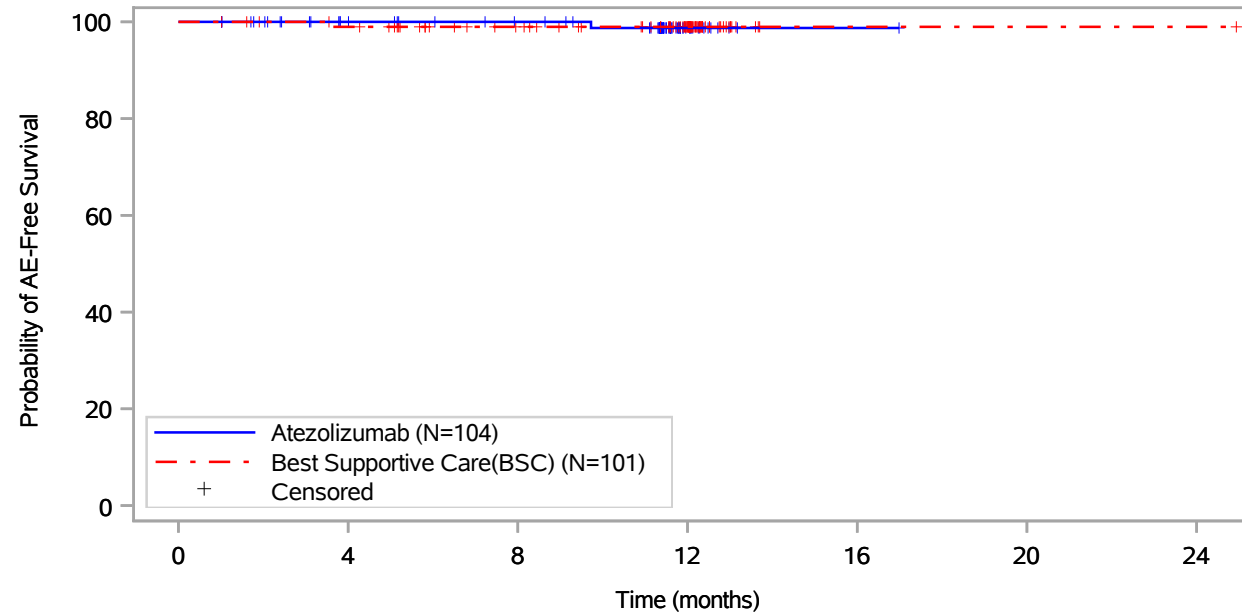
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Ligament sprain



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

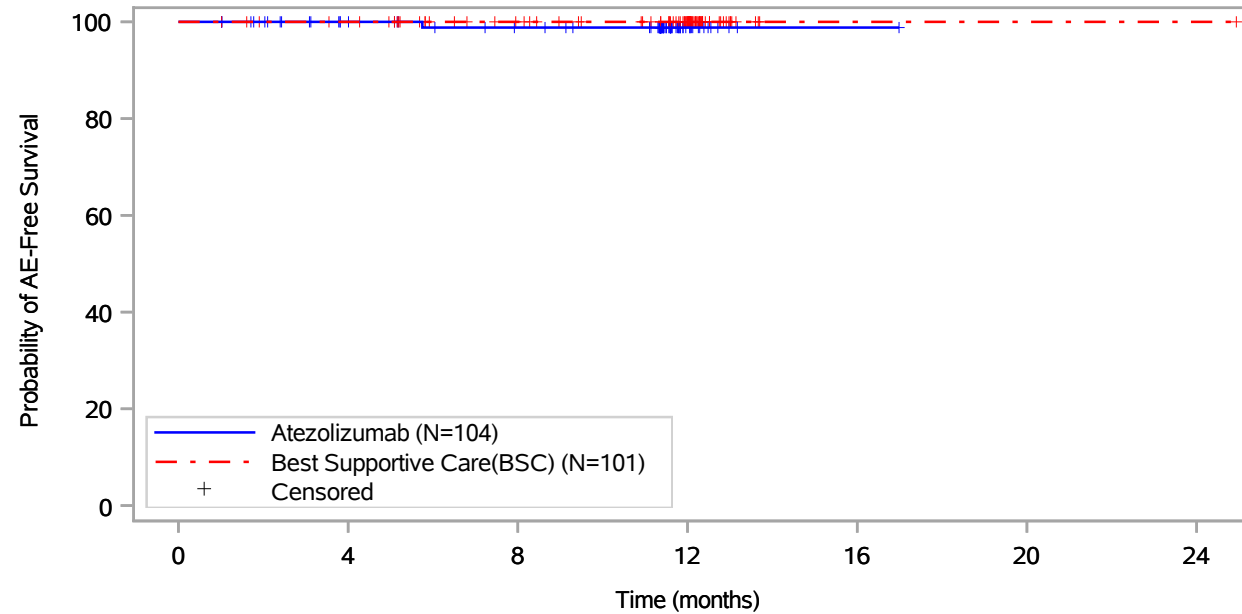
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Limb injury



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

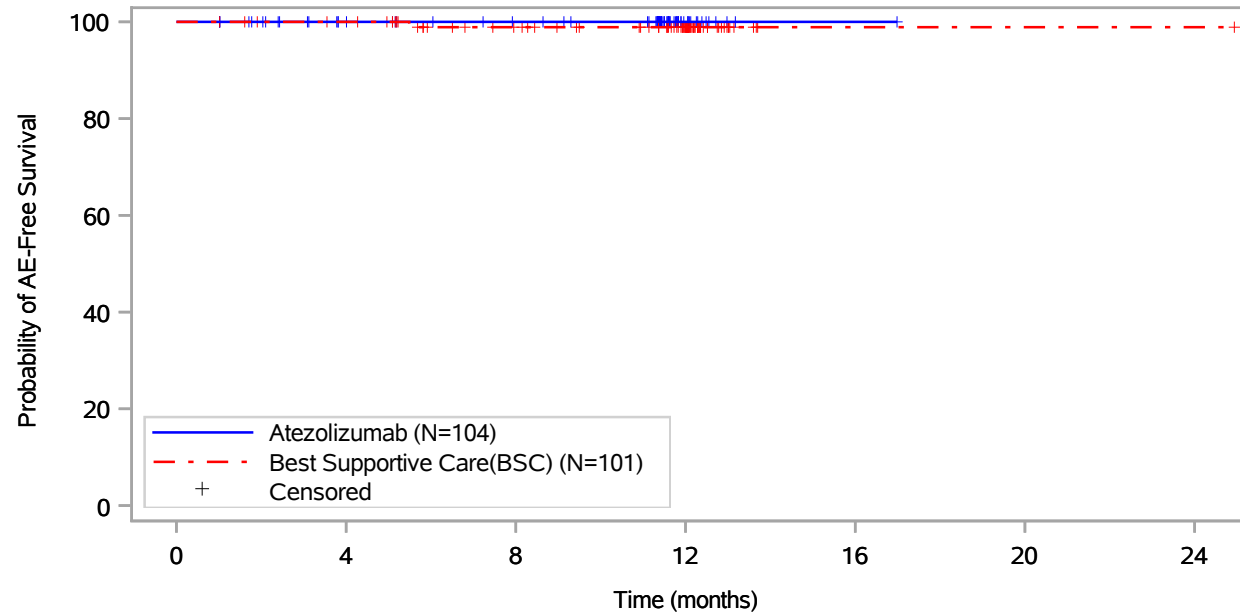
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Rib fracture



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

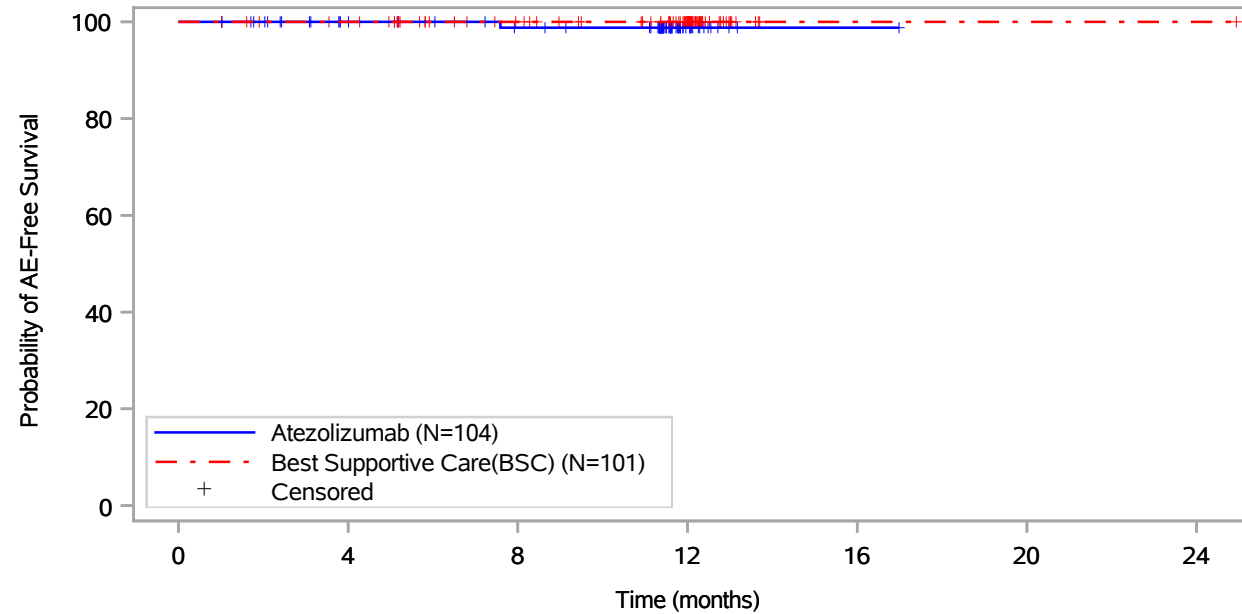
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Injury, poisoning and procedural complications, Vascular access site pain



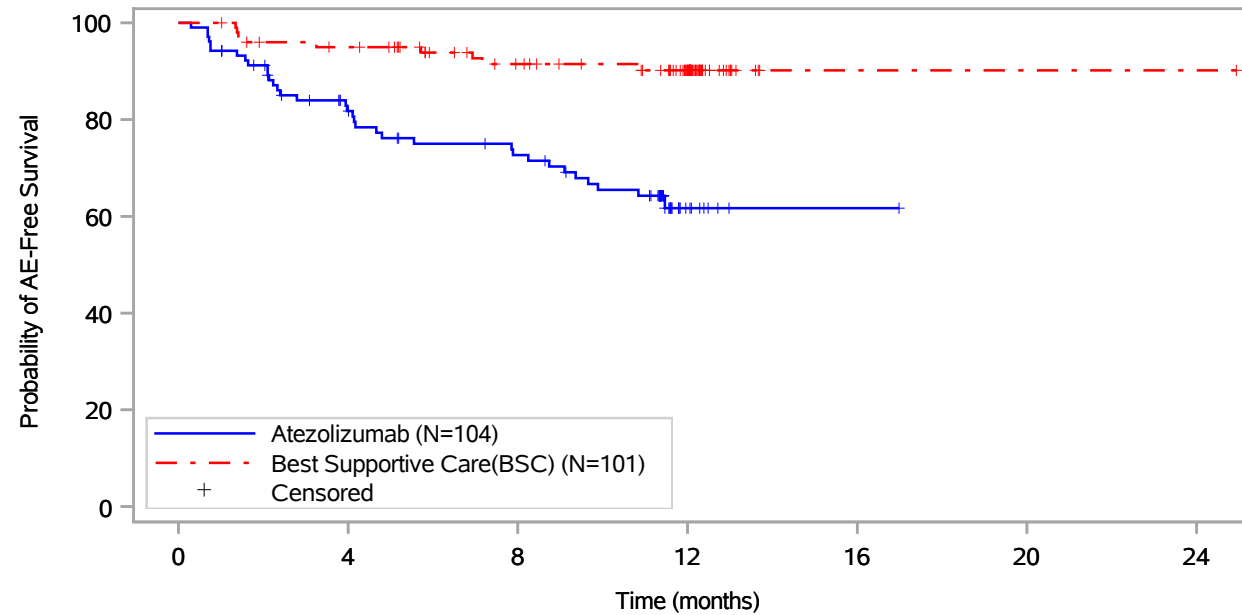
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, All



Patients at risk							
Atezolizumab (N=104)	104	74	62	8	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	92	75	50	1	1	1
Patients censored							
Atezolizumab (N=104)	0	12	16	62	69	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	42	91	91	91

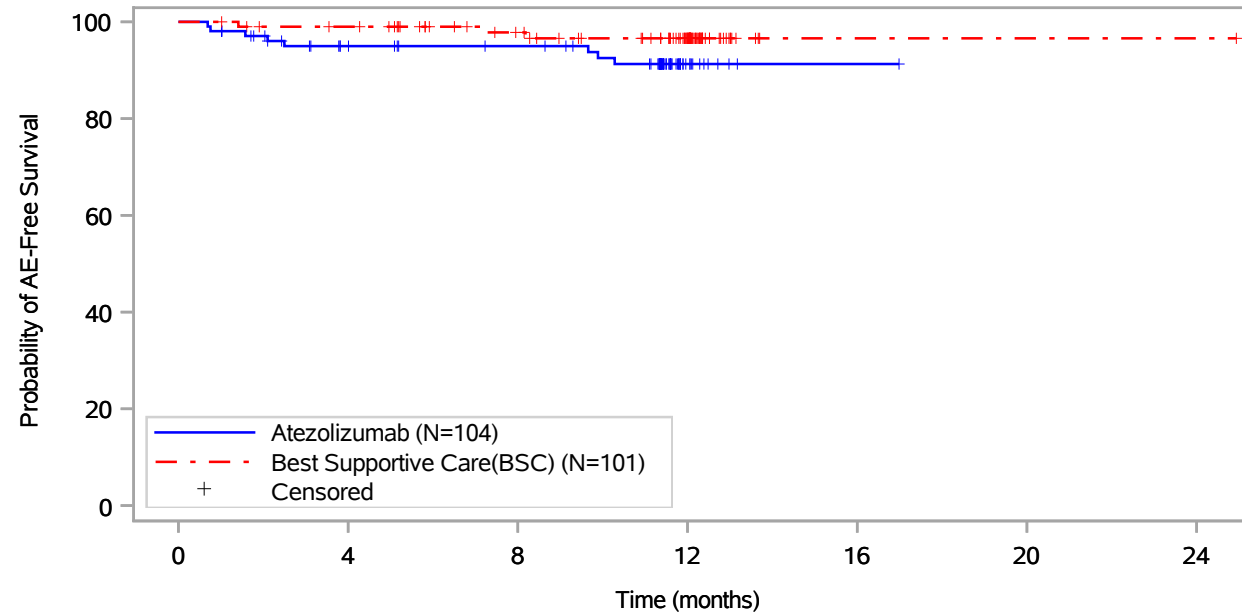
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk							
Atezolizumab (N=104)	104	85	80	11	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	52	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	85	95	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	97	97	97

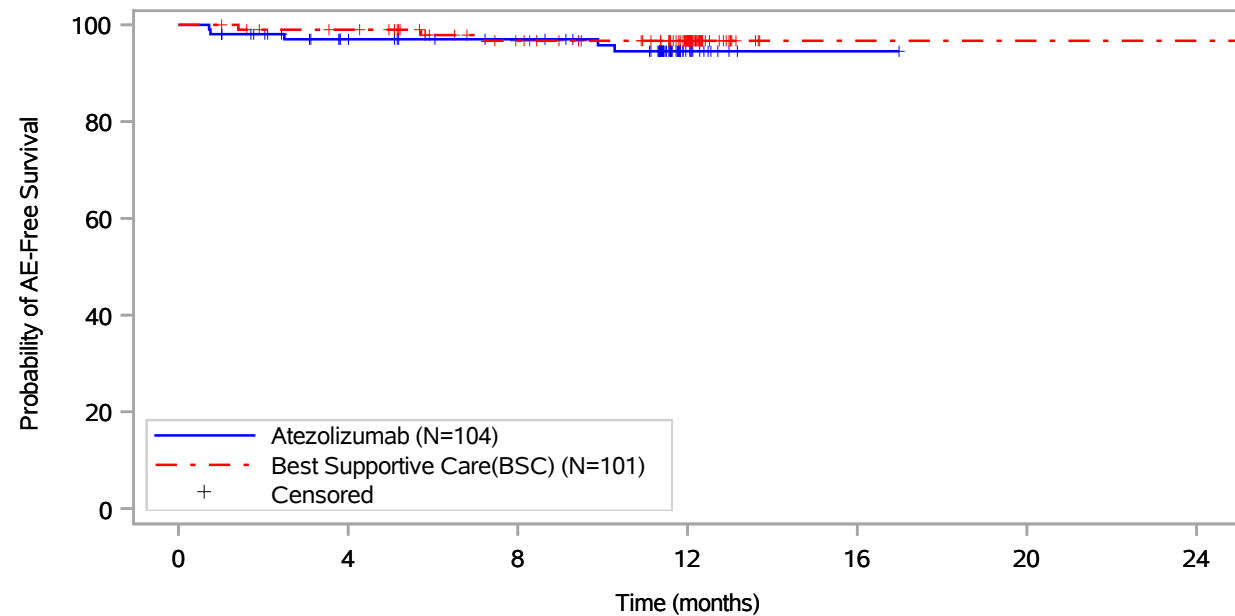
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	81	12	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	80	52	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	20	87	98	97	97	97
Best Supportive Care(BSC) (N=101)	0	4	18	46	97	97	97	97

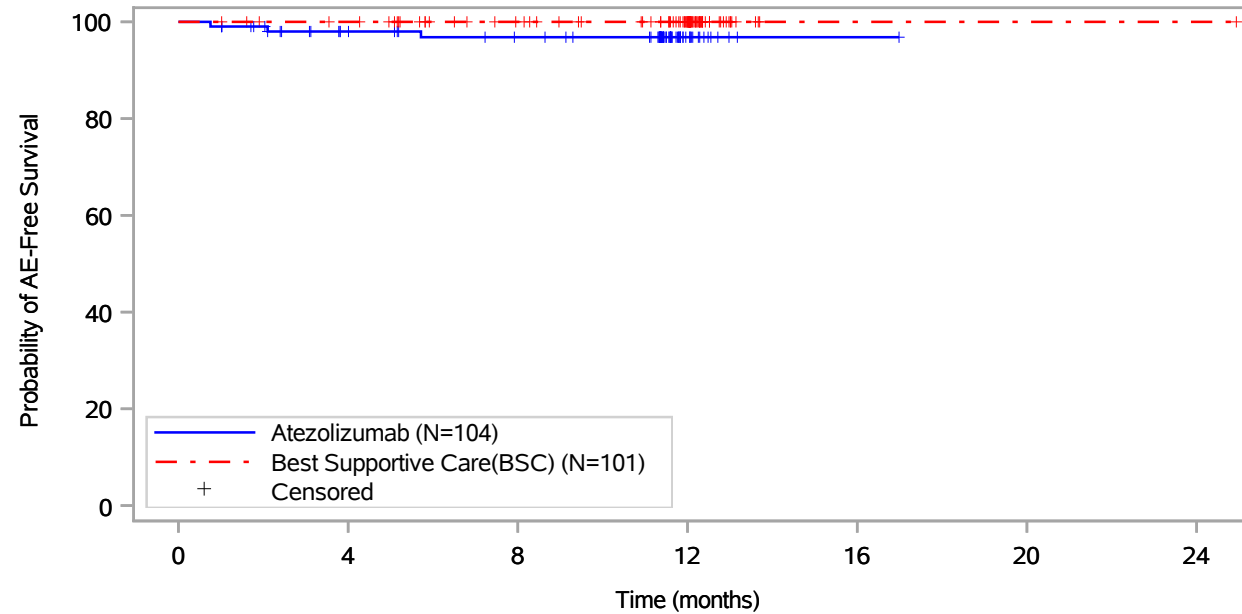
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood alkaline phosphatase increased



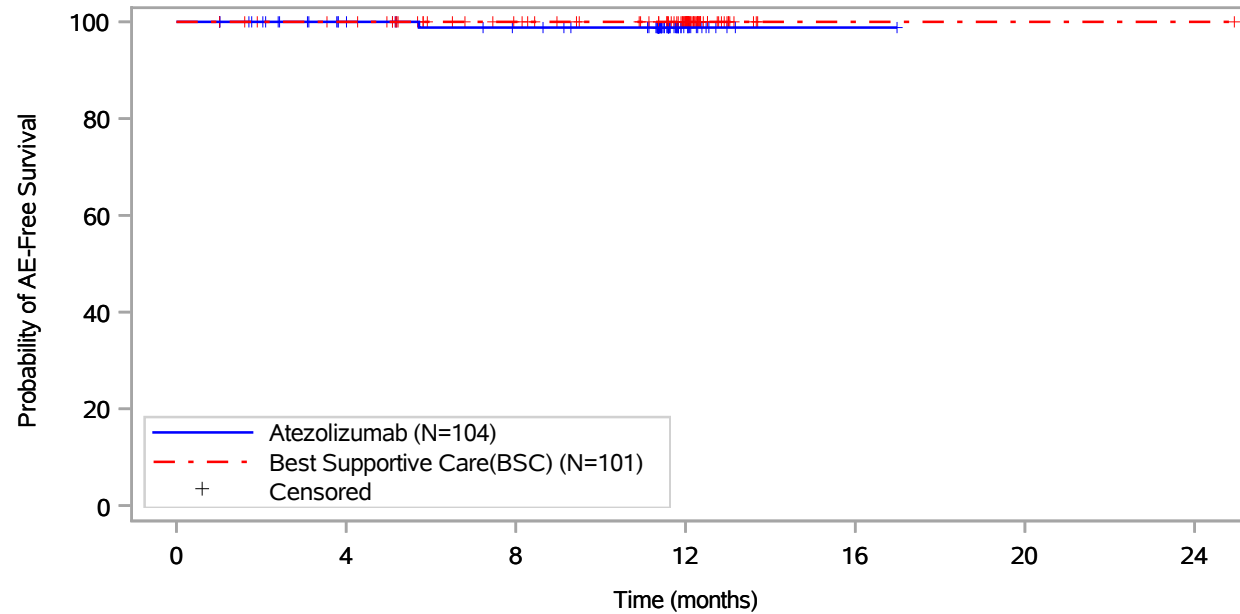
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	80	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	87	100	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Blood bilirubin increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

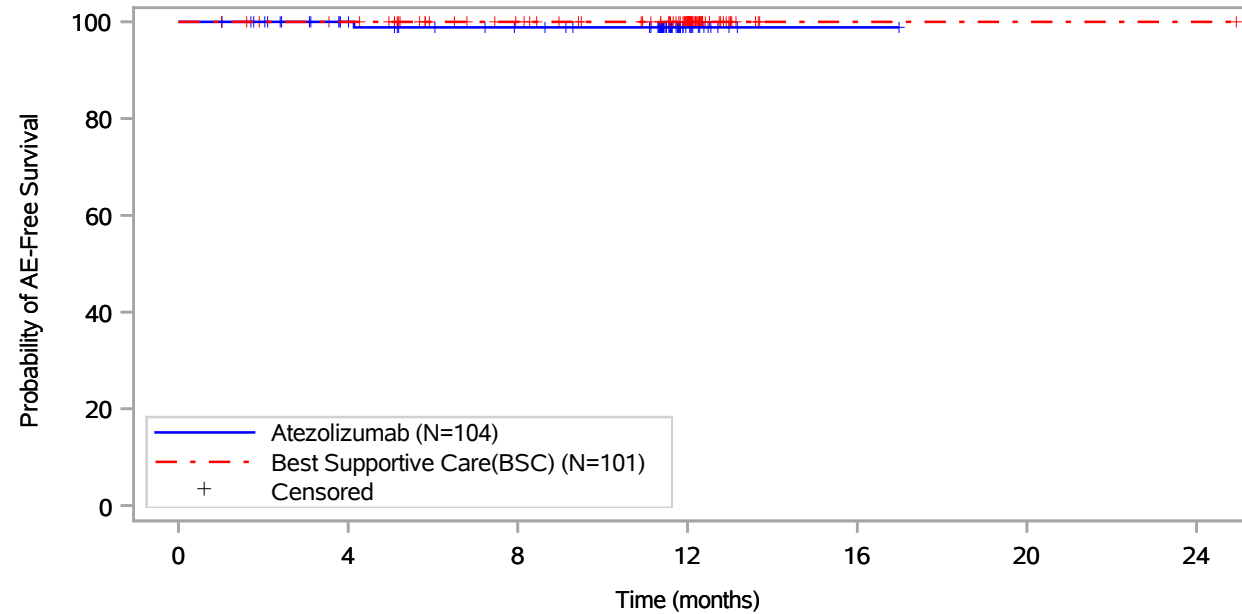
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood cholesterol increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

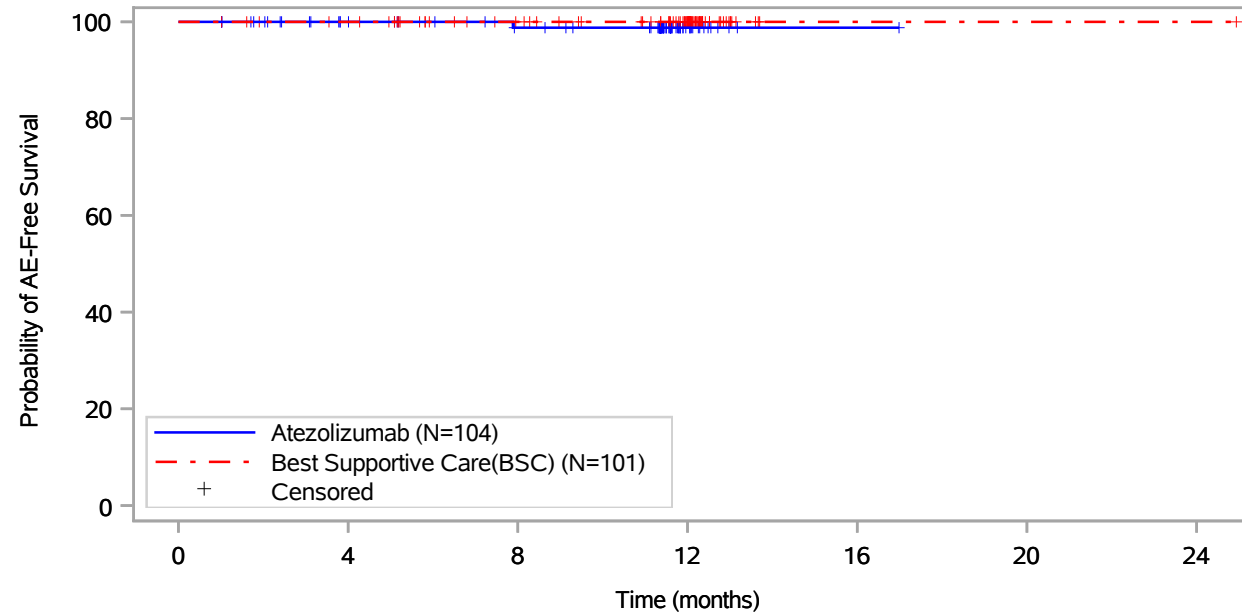
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood creatine increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

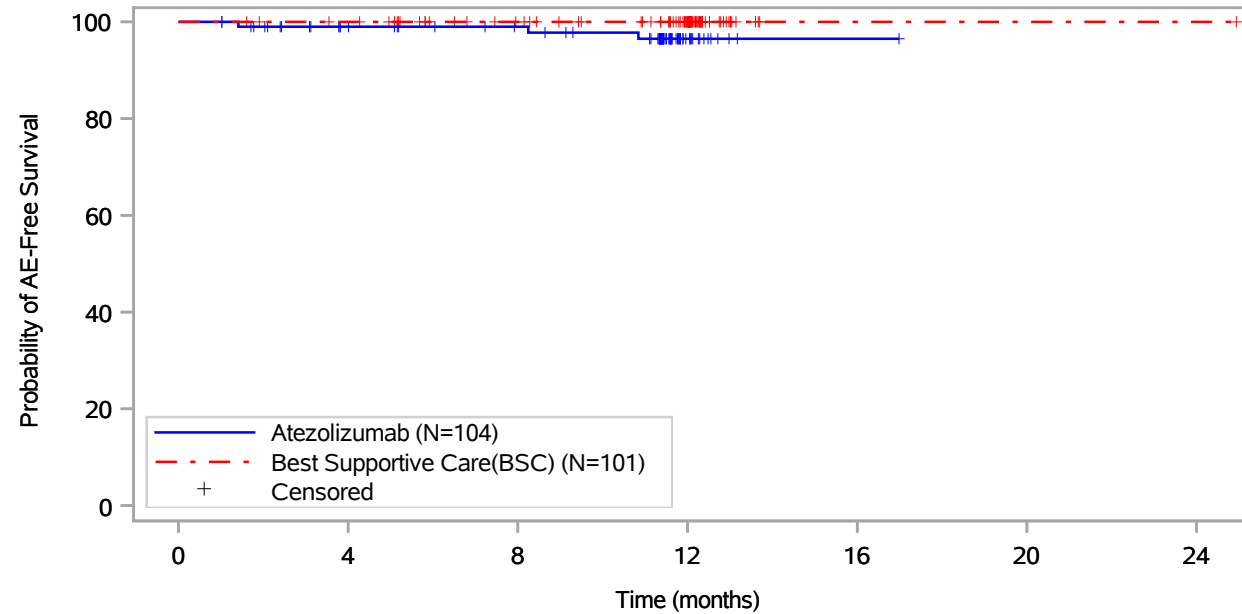
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood creatine phosphokinase increased



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

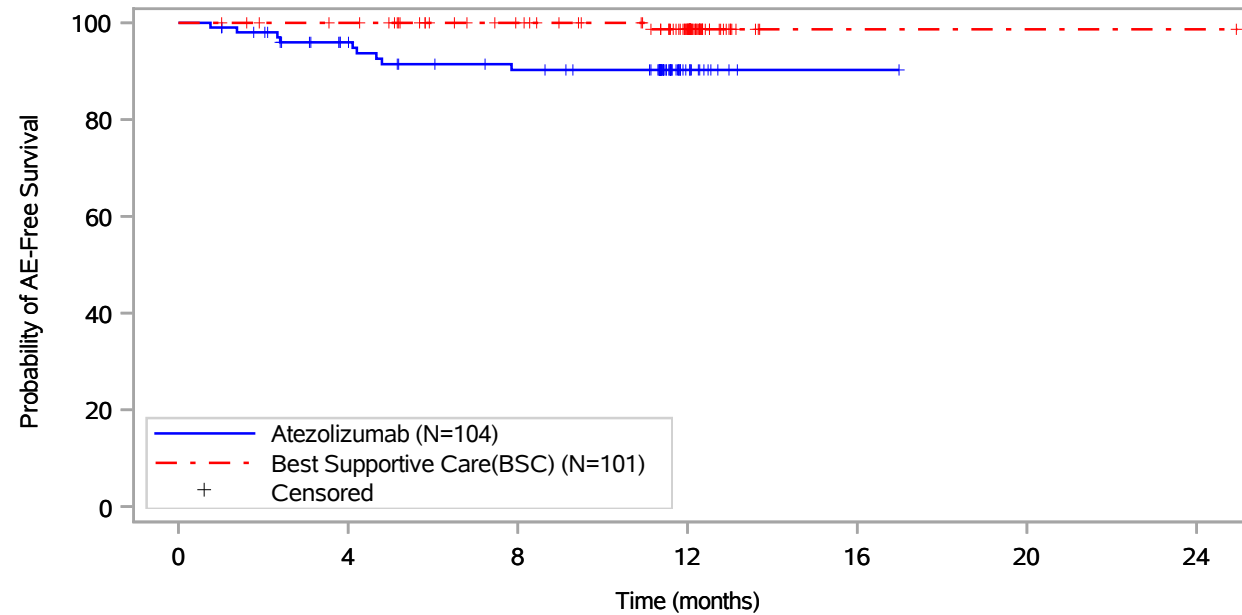
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood creatinine increased



Patients at risk							
Atezolizumab (N=104)	104	86	76	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	82	94	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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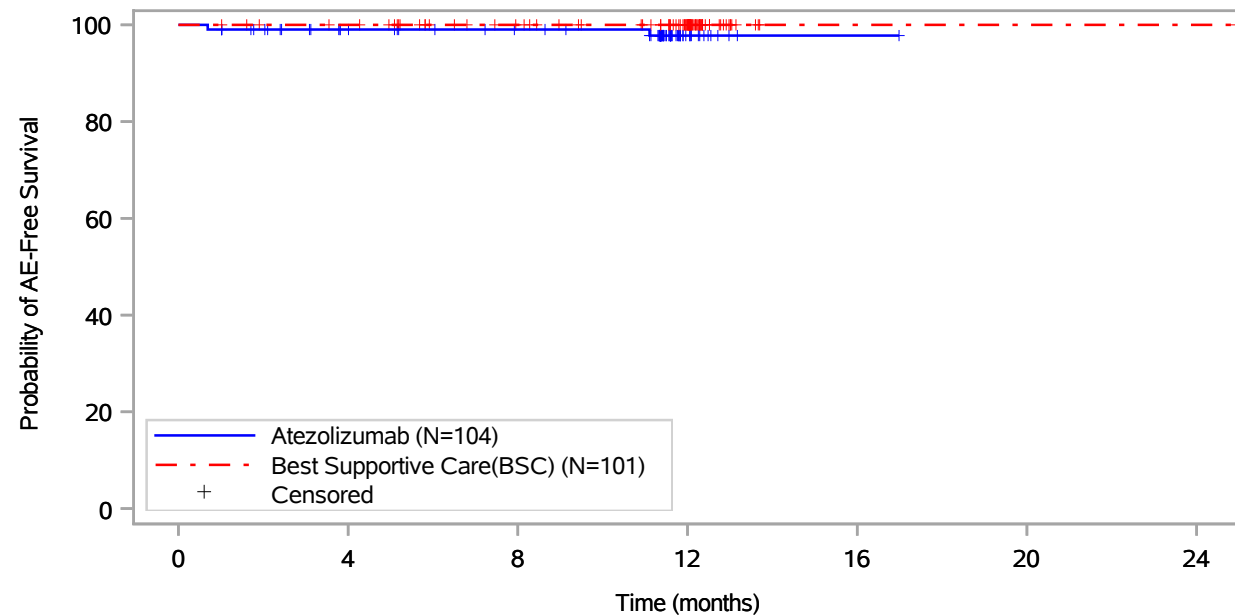
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood iron decreased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

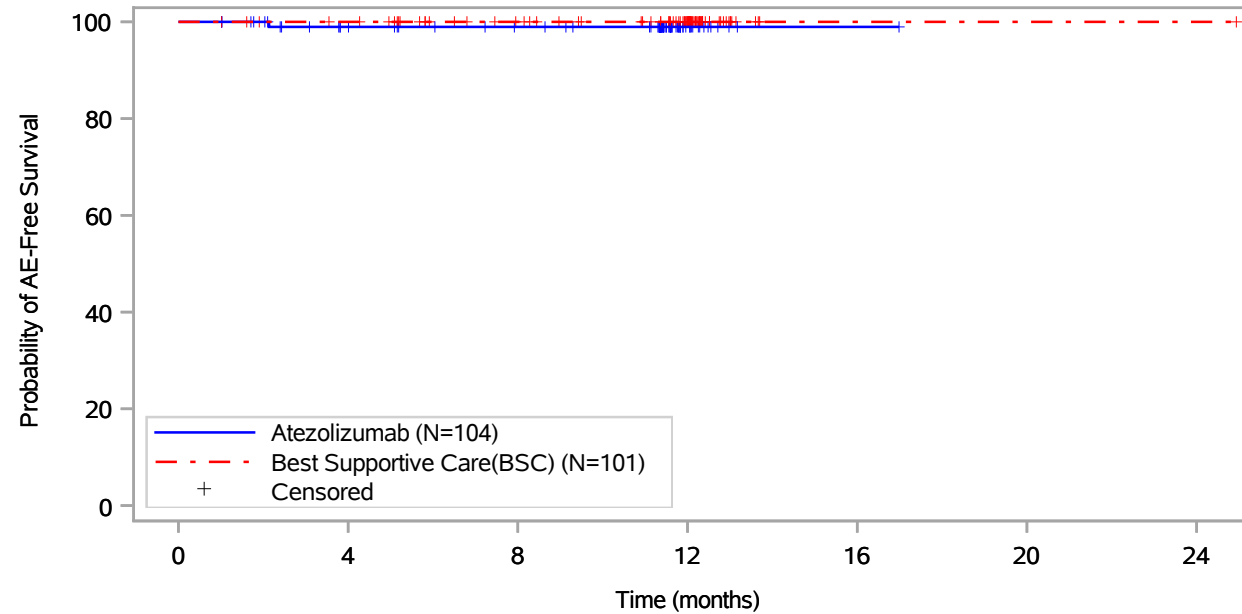
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood lactate dehydrogenase increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

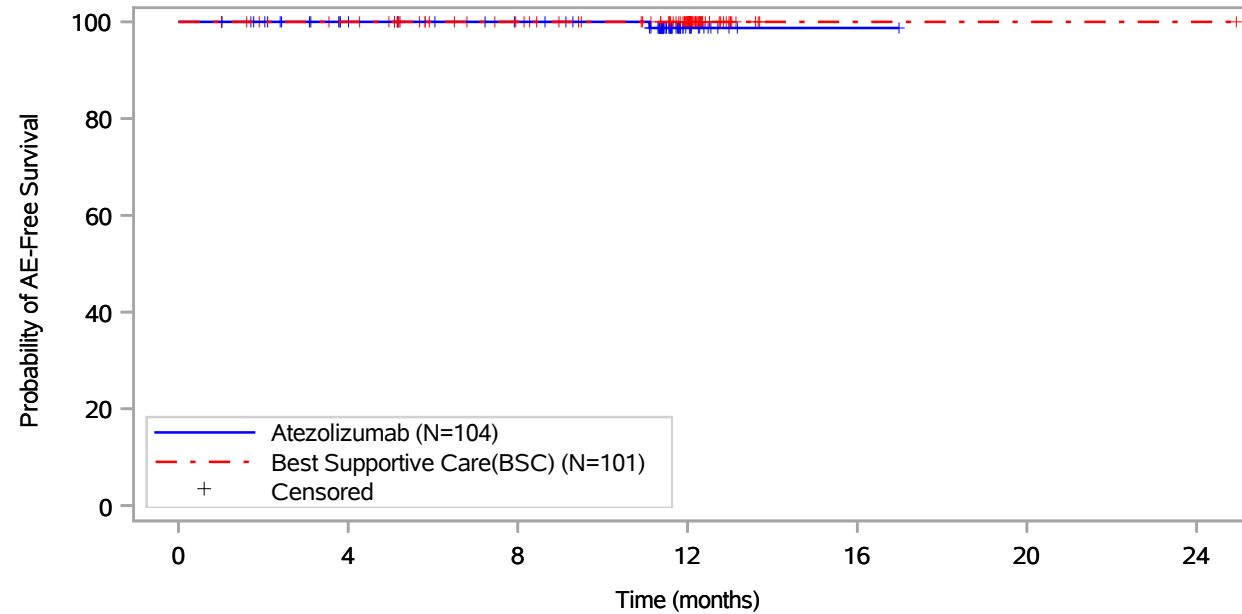
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood magnesium decreased



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

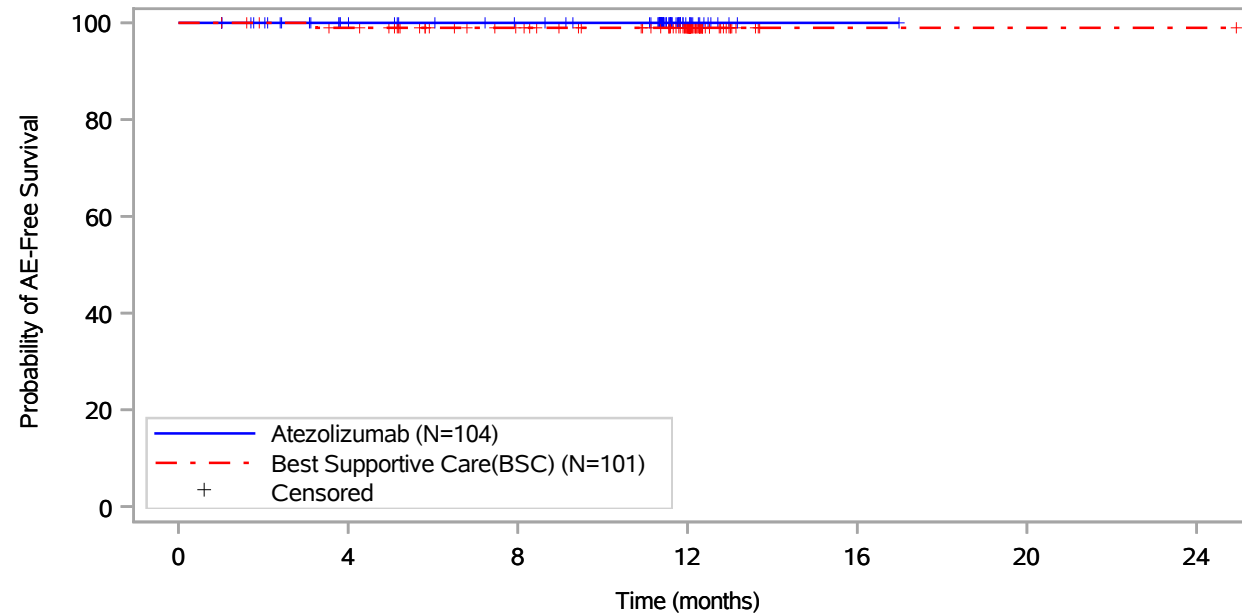
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood pressure increased



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

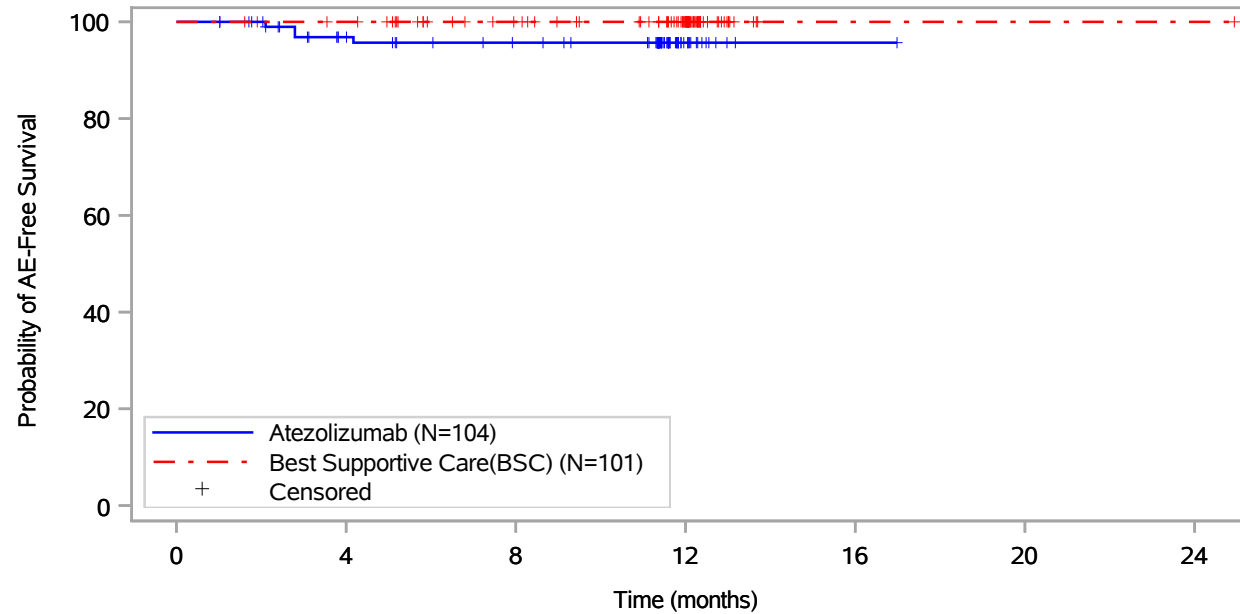
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood thyroid stimulating hormone decreased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	86	78	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	86	99	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

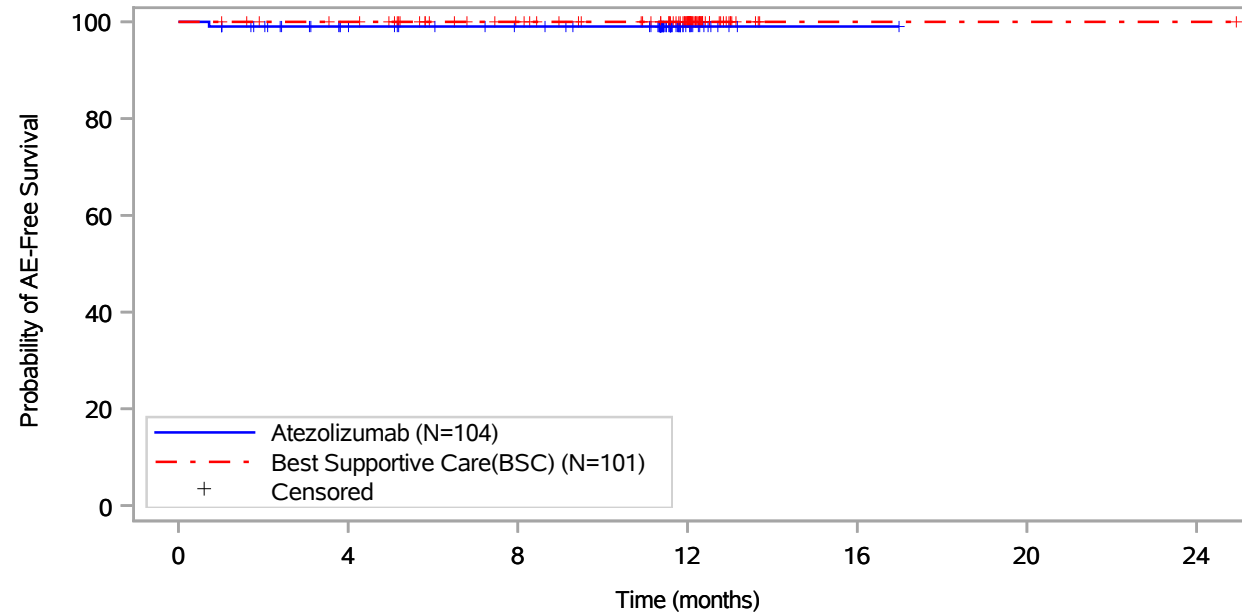
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Blood triglycerides increased



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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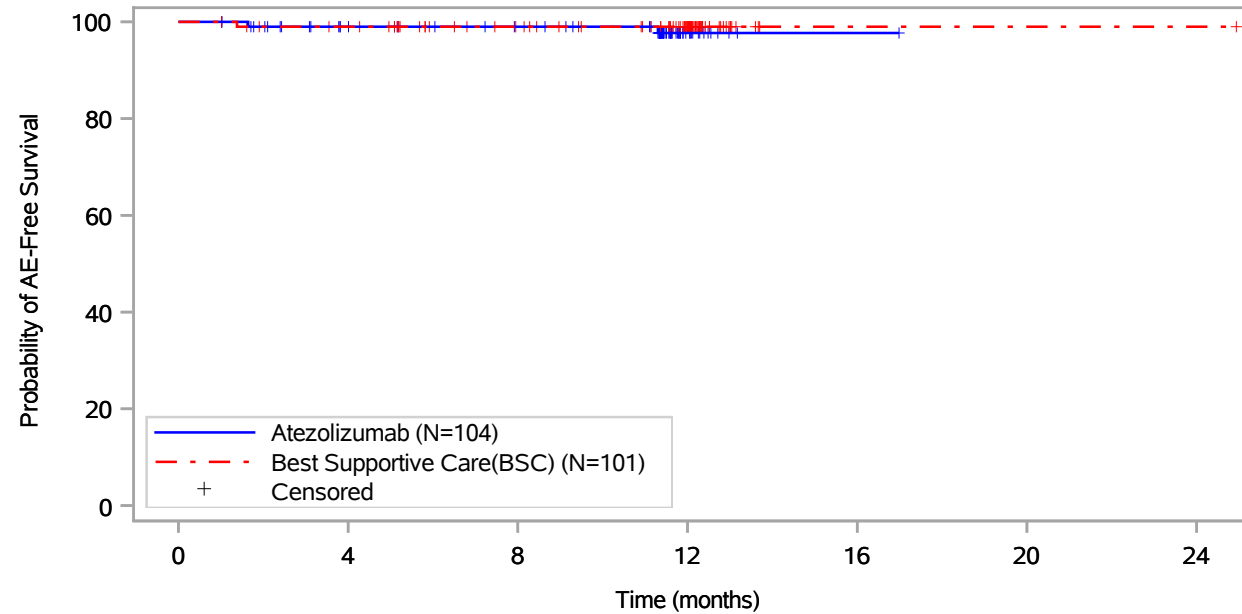
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Investigations, Blood uric acid increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	88	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

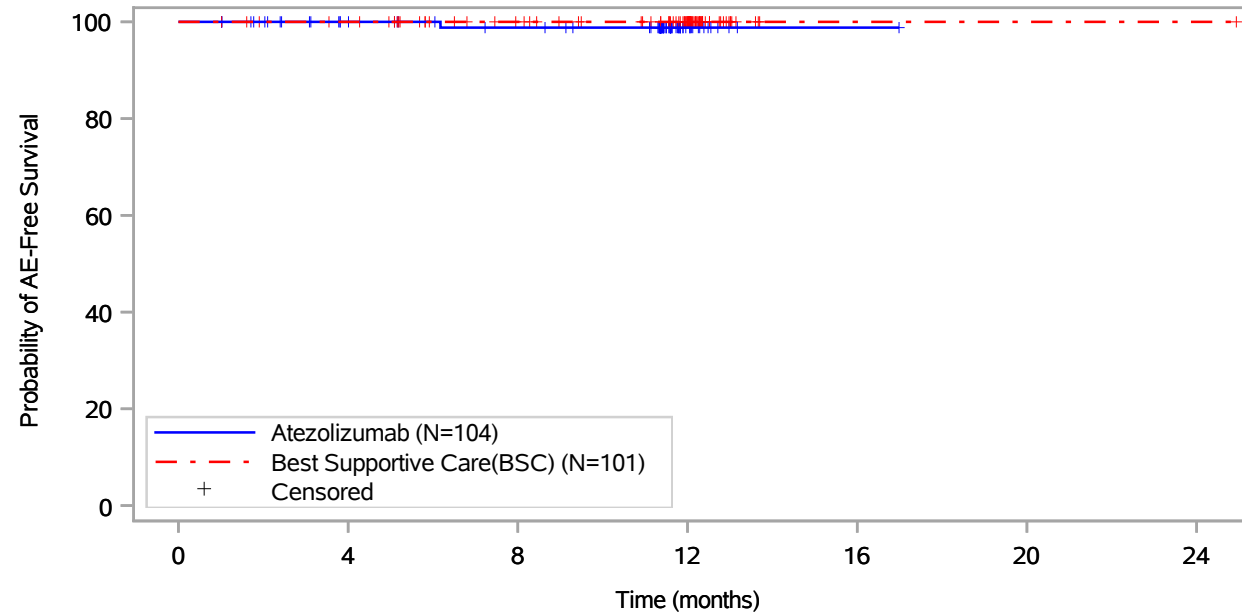
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Creatinine renal clearance decreased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

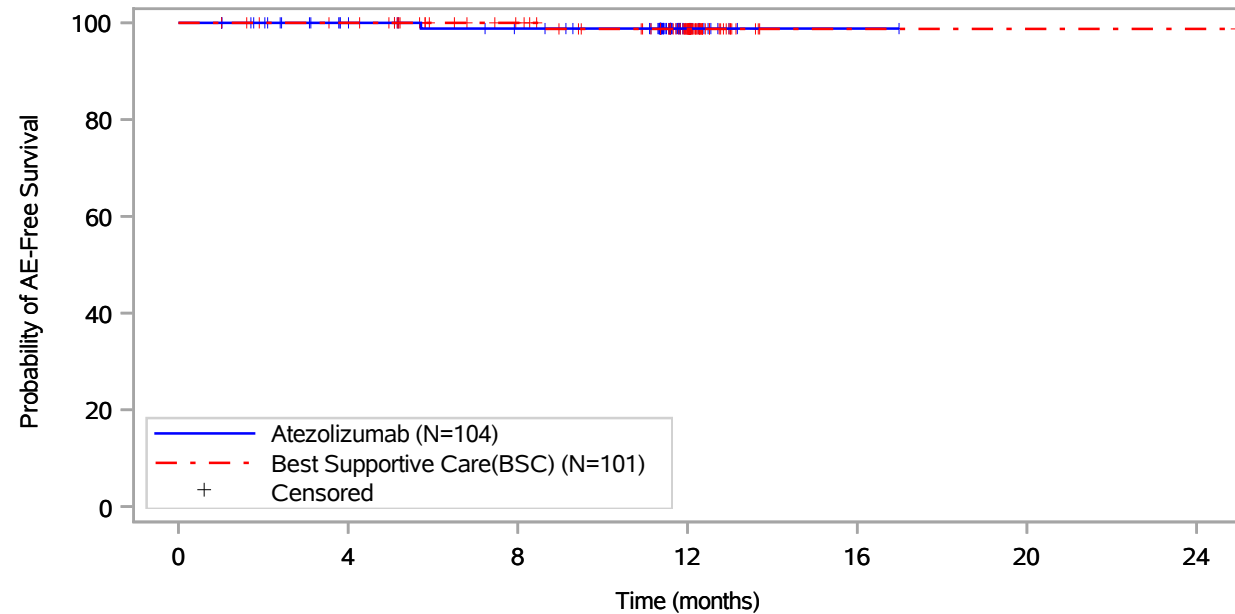
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Gamma-glutamyltransferase increased



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

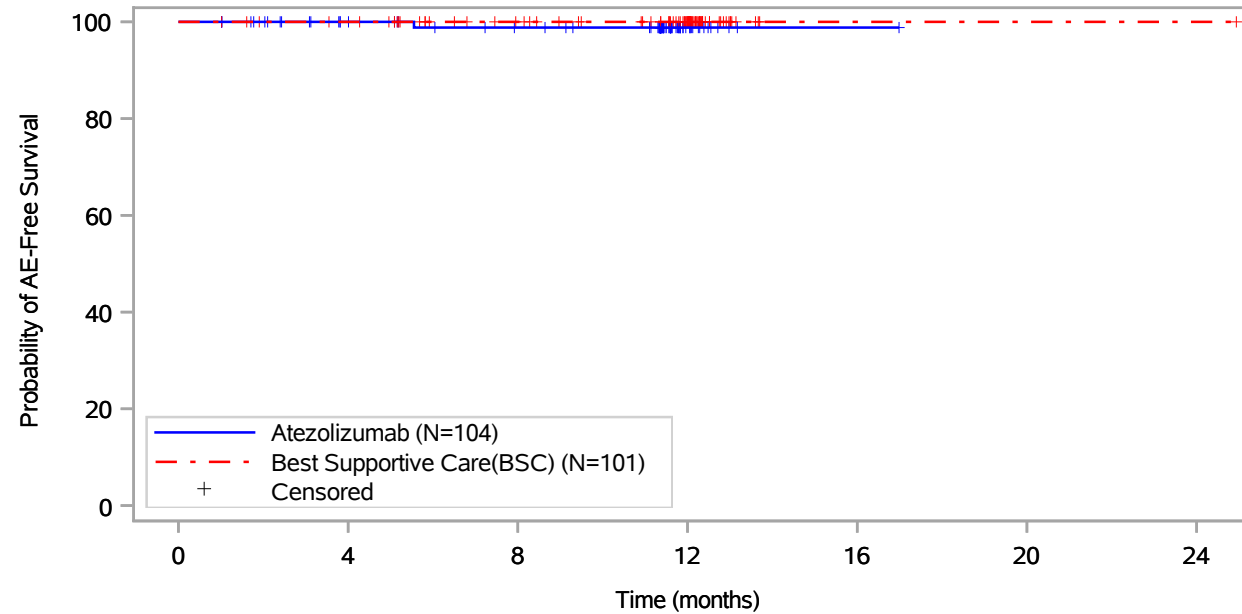
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Gastric pH decreased



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

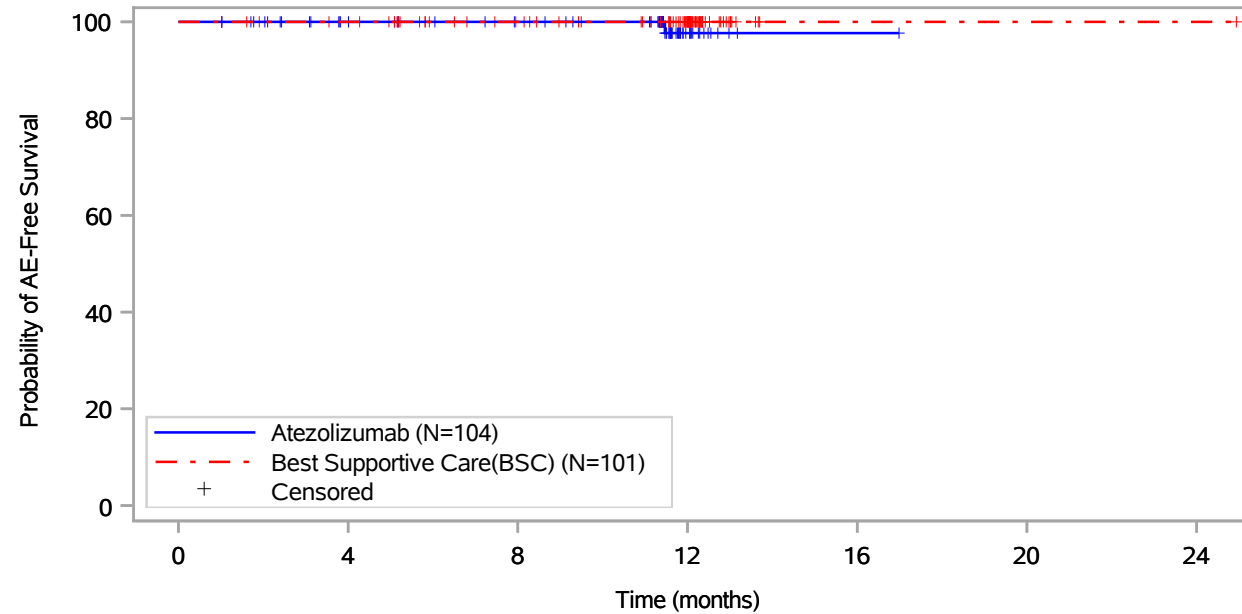
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, International normalised ratio increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

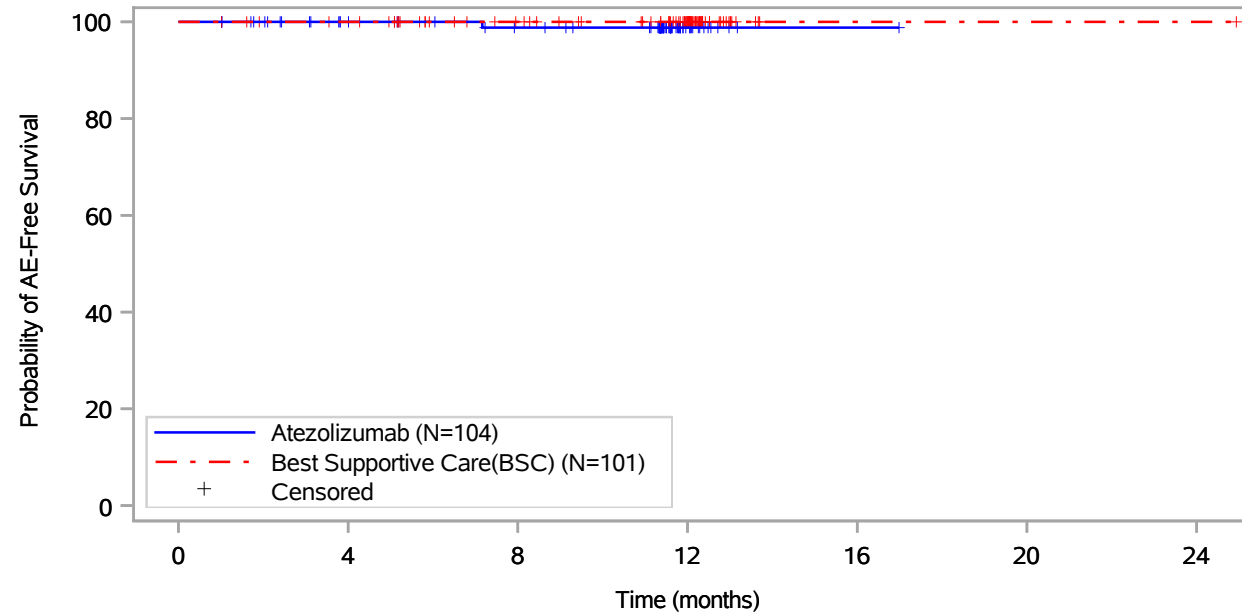
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Liver function test increased



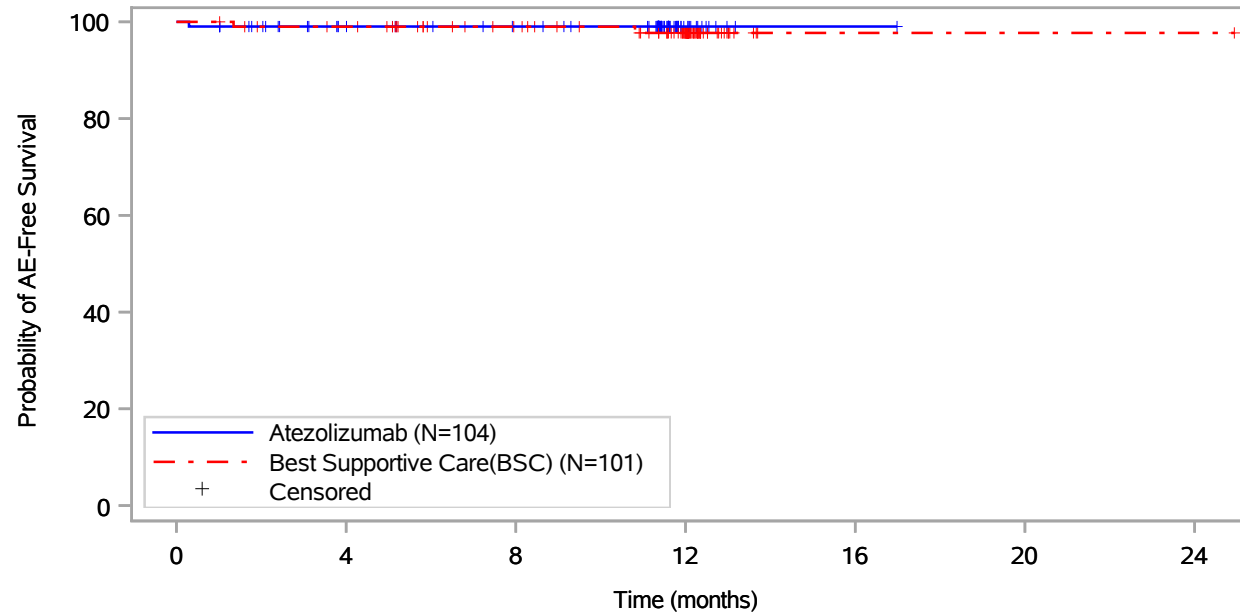
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Neutrophil count decreased



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	98	98	98

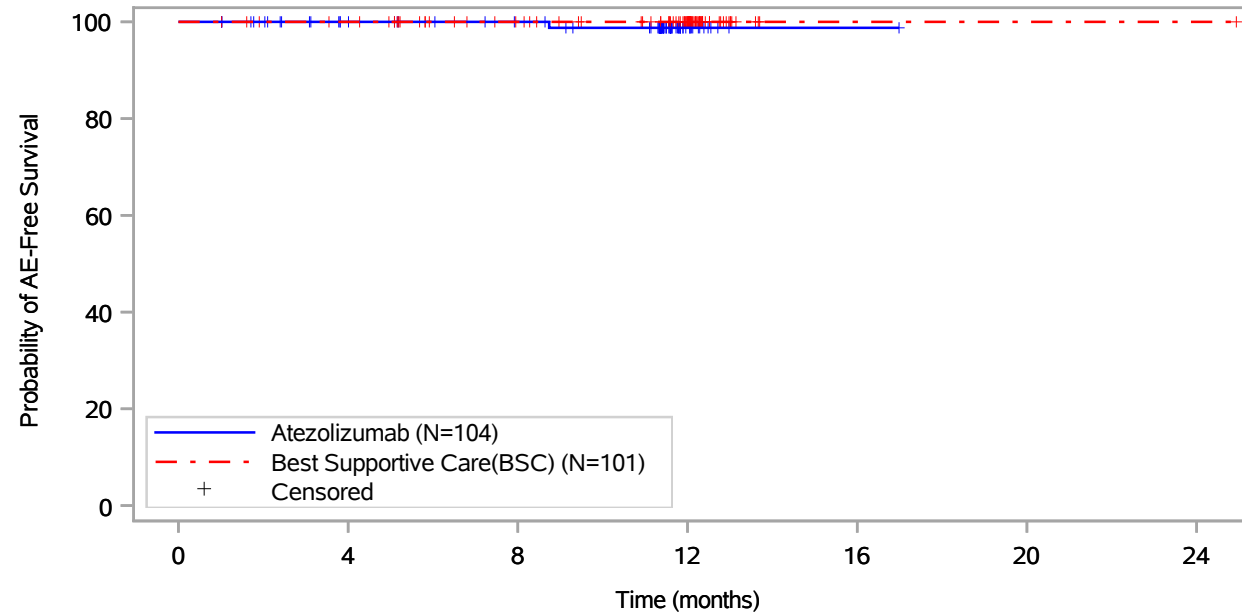
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Investigations, Oxygen saturation decreased



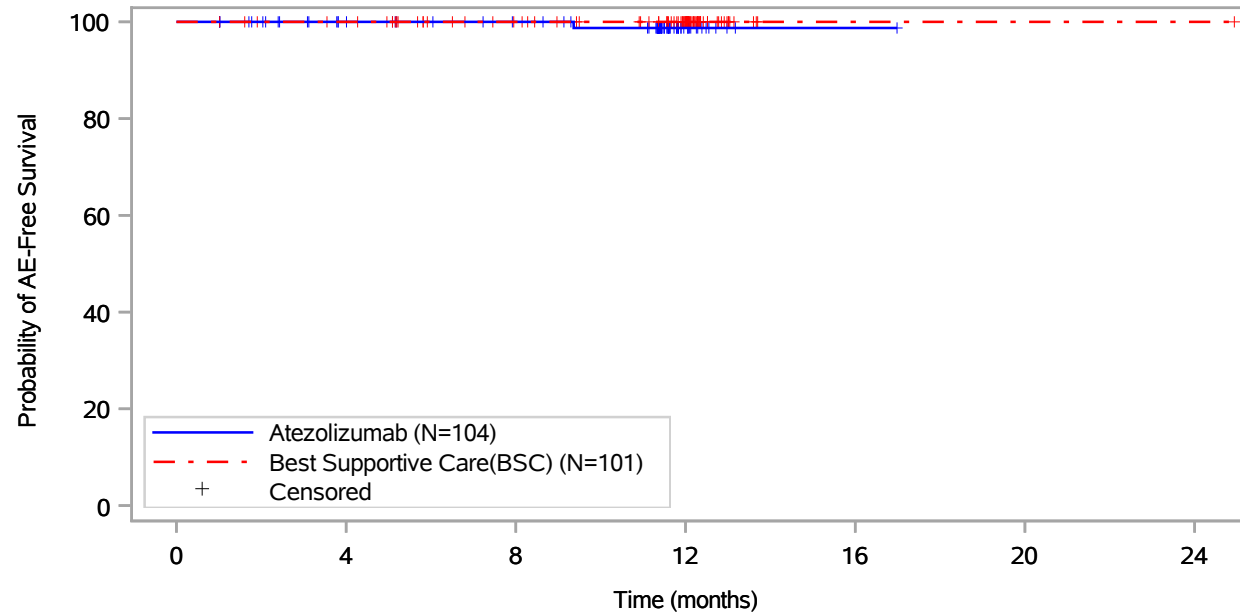
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Transaminases increased



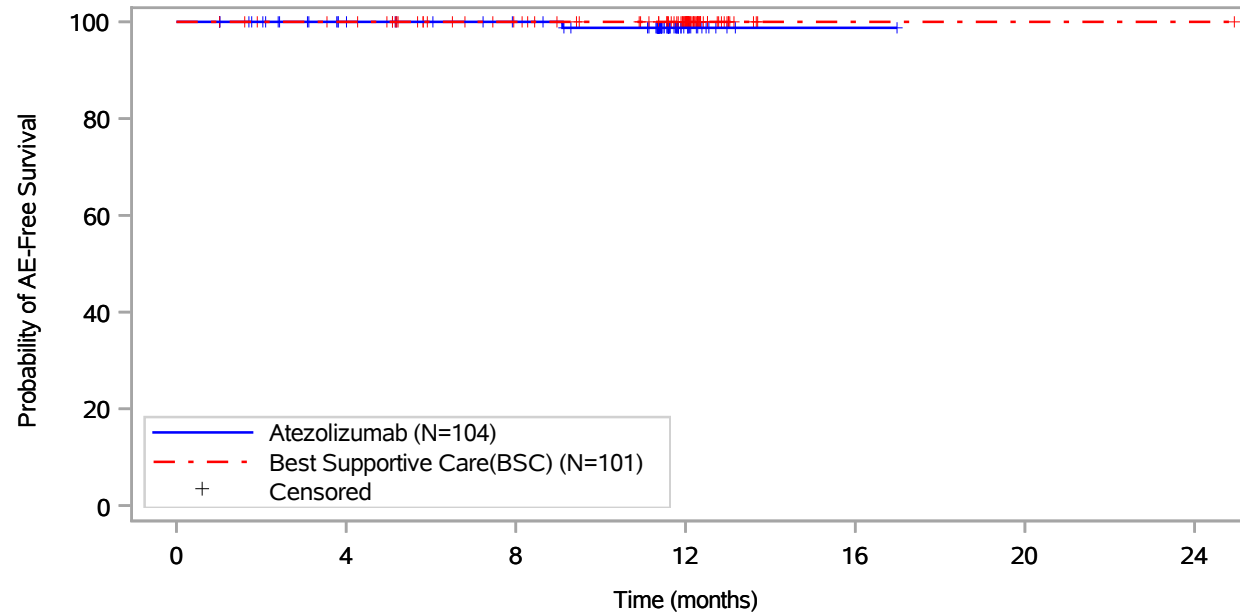
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Urine bilirubin increased



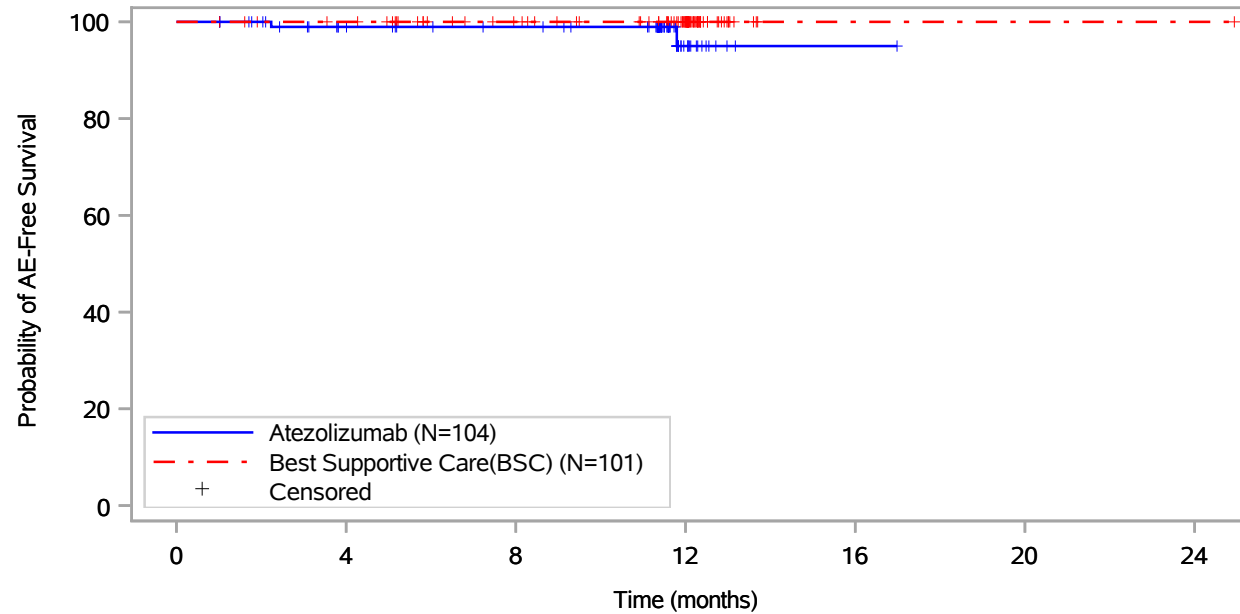
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Weight decreased



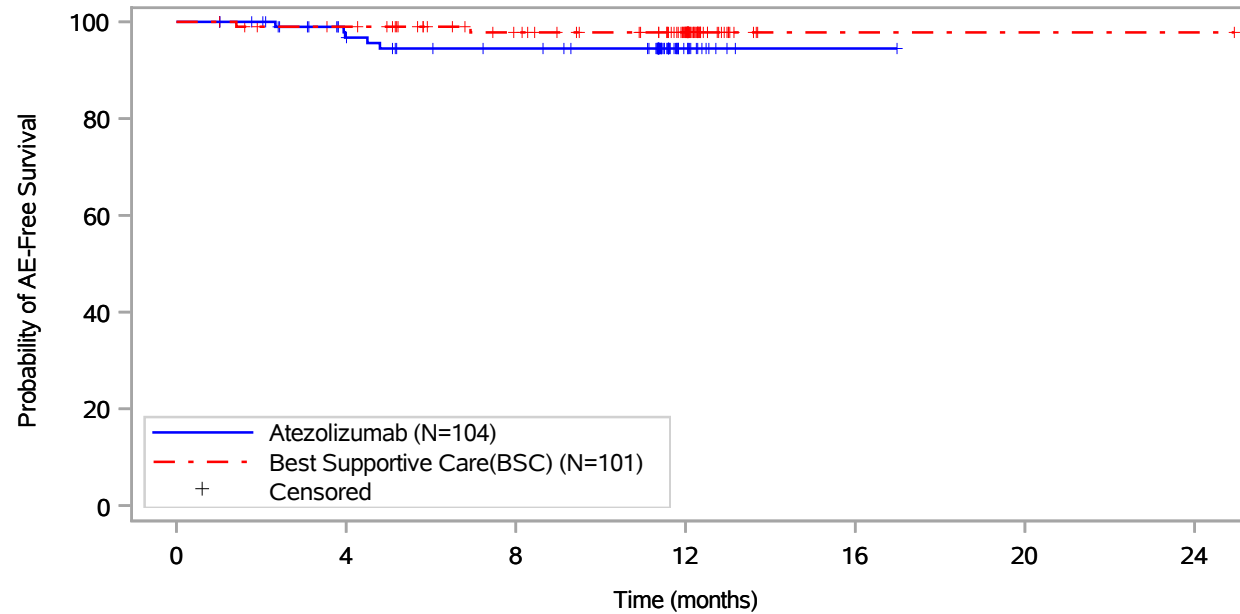
Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Investigations, Weight increased



Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	85	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98

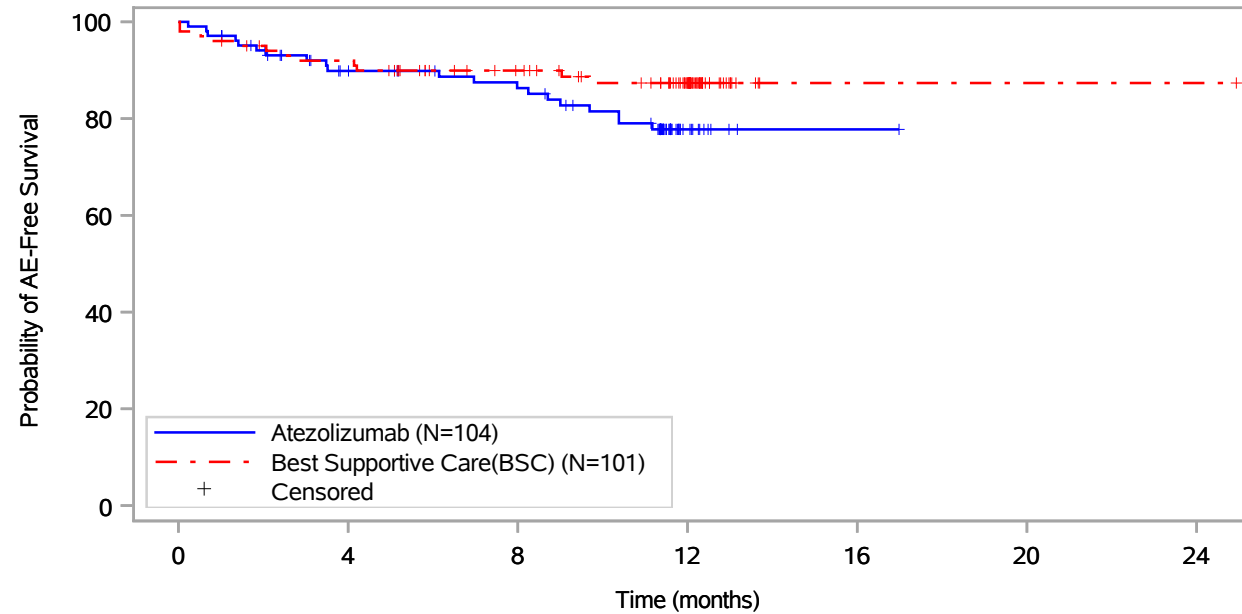
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk							
Atezolizumab (N=104)	104	81	73	11	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	90	75	48	1	1	1
Patients censored							
Atezolizumab (N=104)	0	13	18	73	83	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	16	41	88	88	88

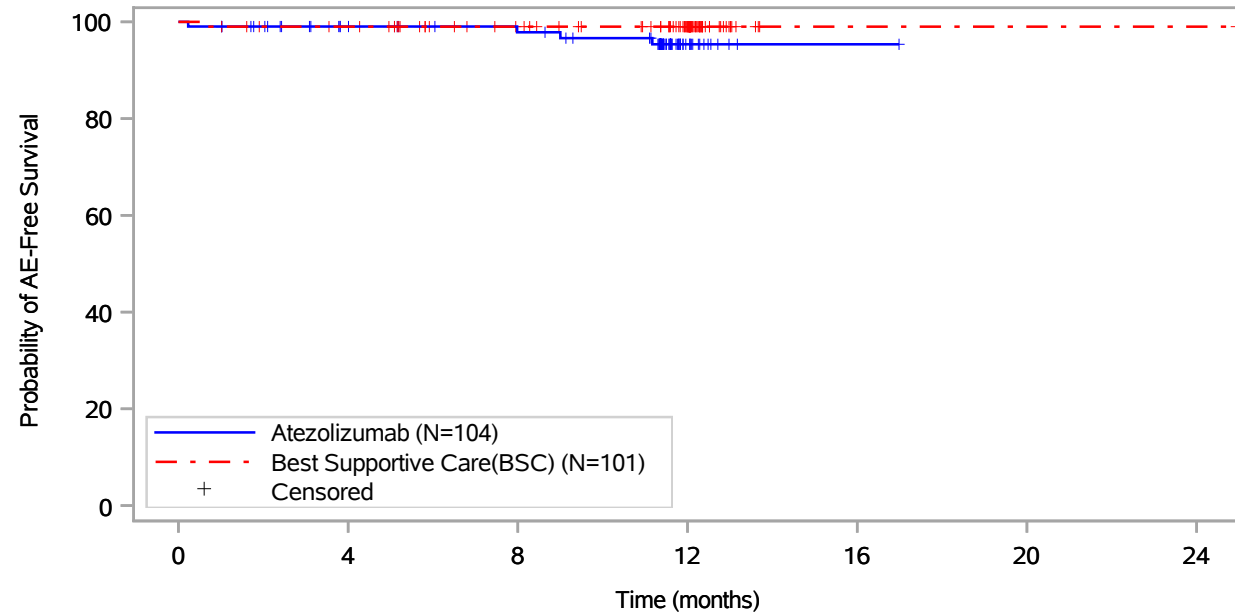
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Decreased appetite



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	20	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

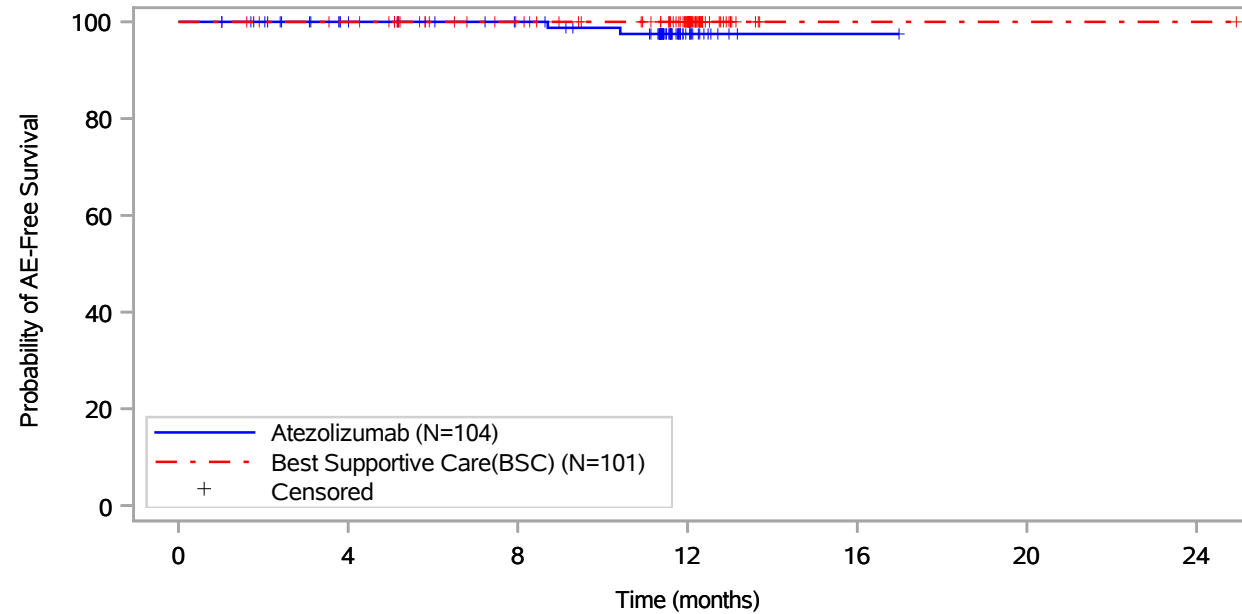
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Dehydration



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

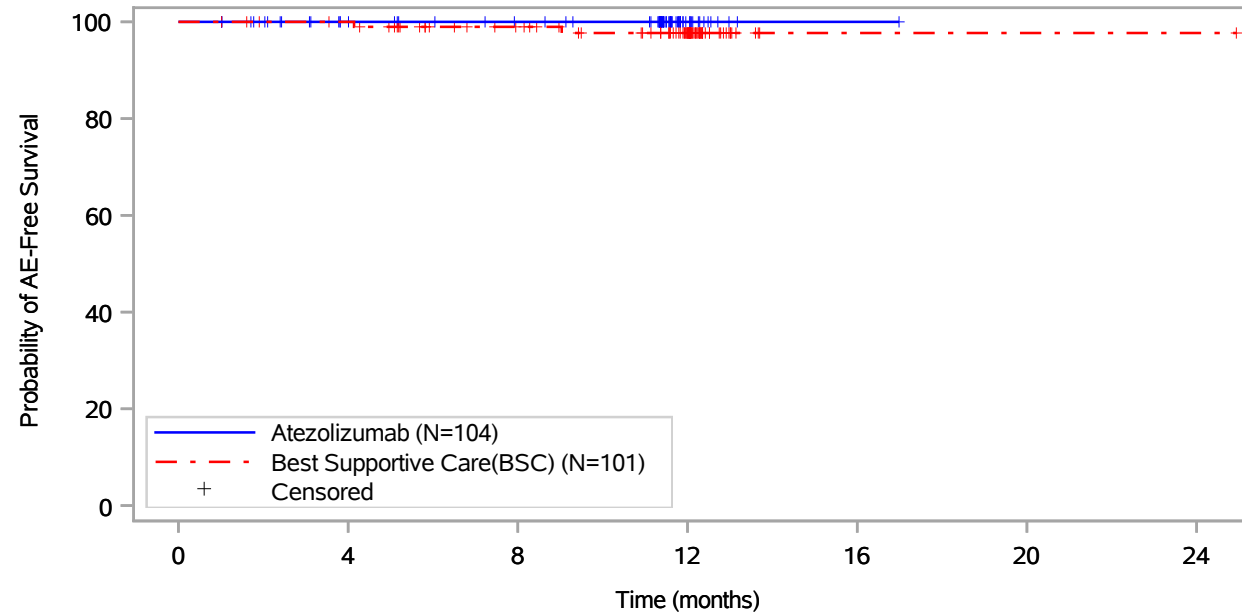
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypercholesterolaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	53	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98	98

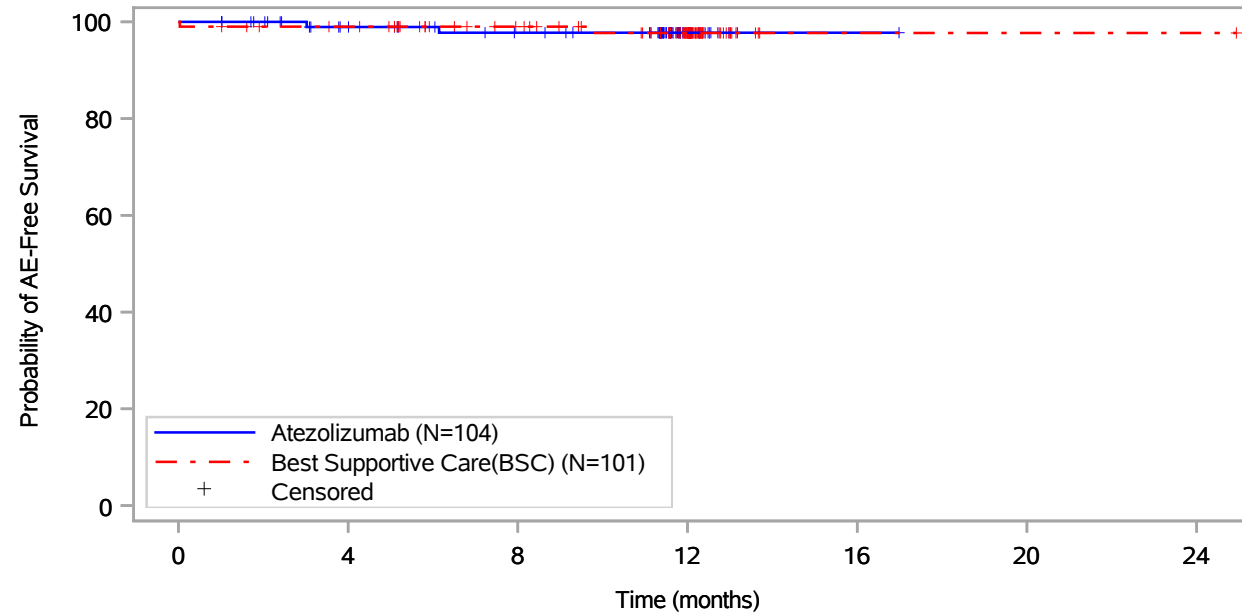
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hyperglycaemia



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

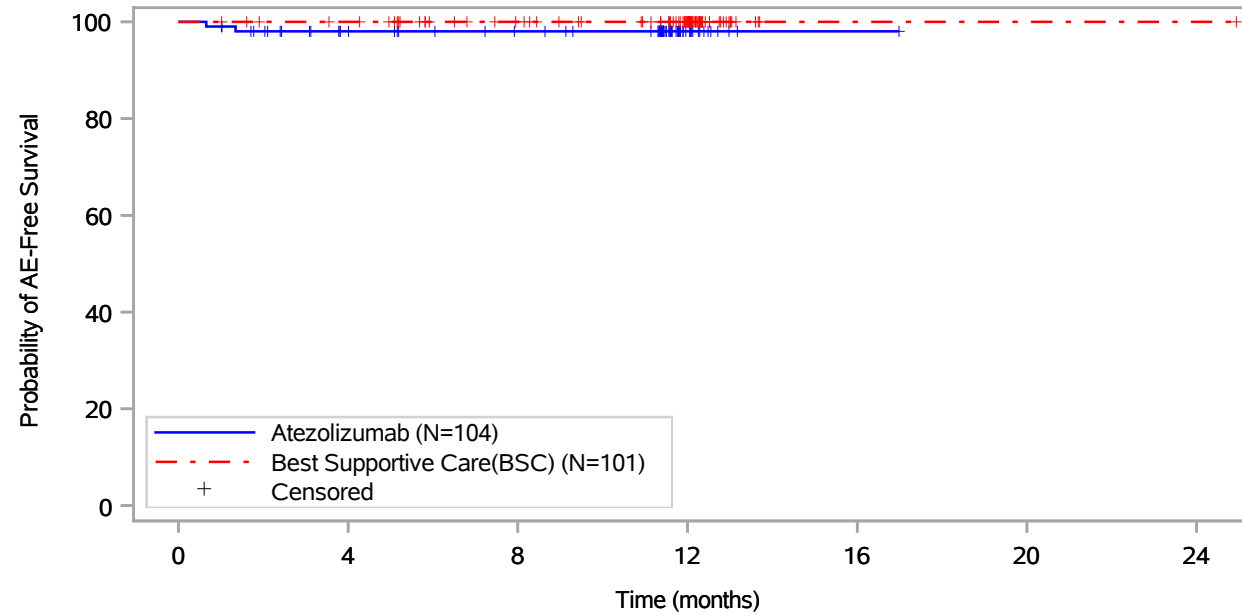
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk							
Atezolizumab (N=104)	104	87	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

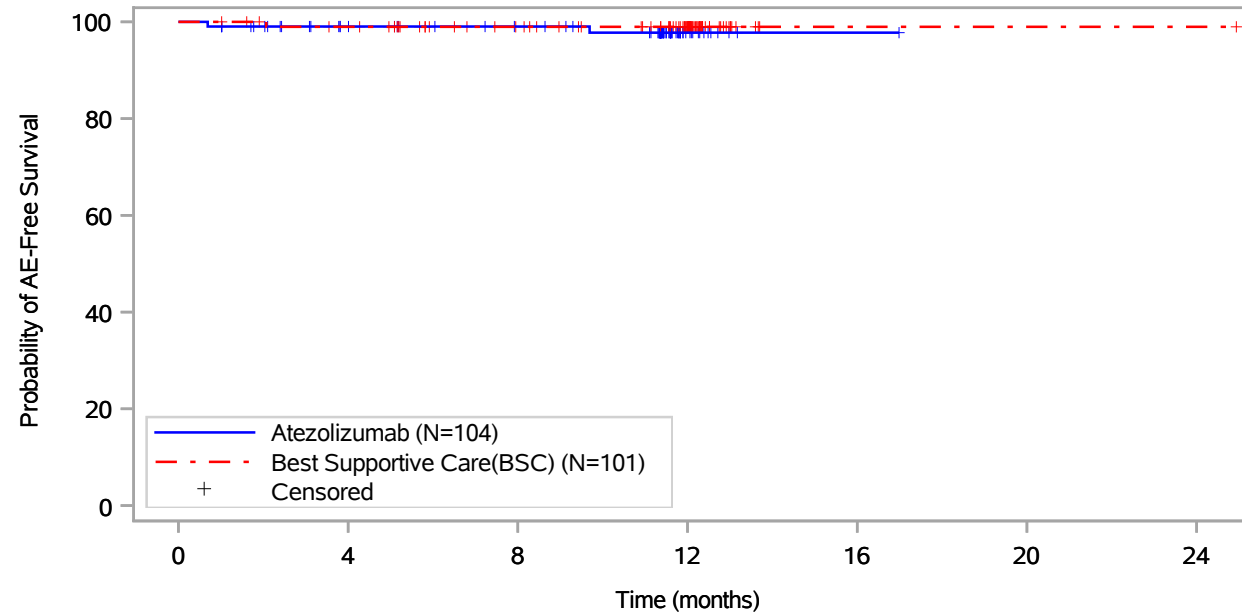
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk							
Atezolizumab (N=104)	104	88	81	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

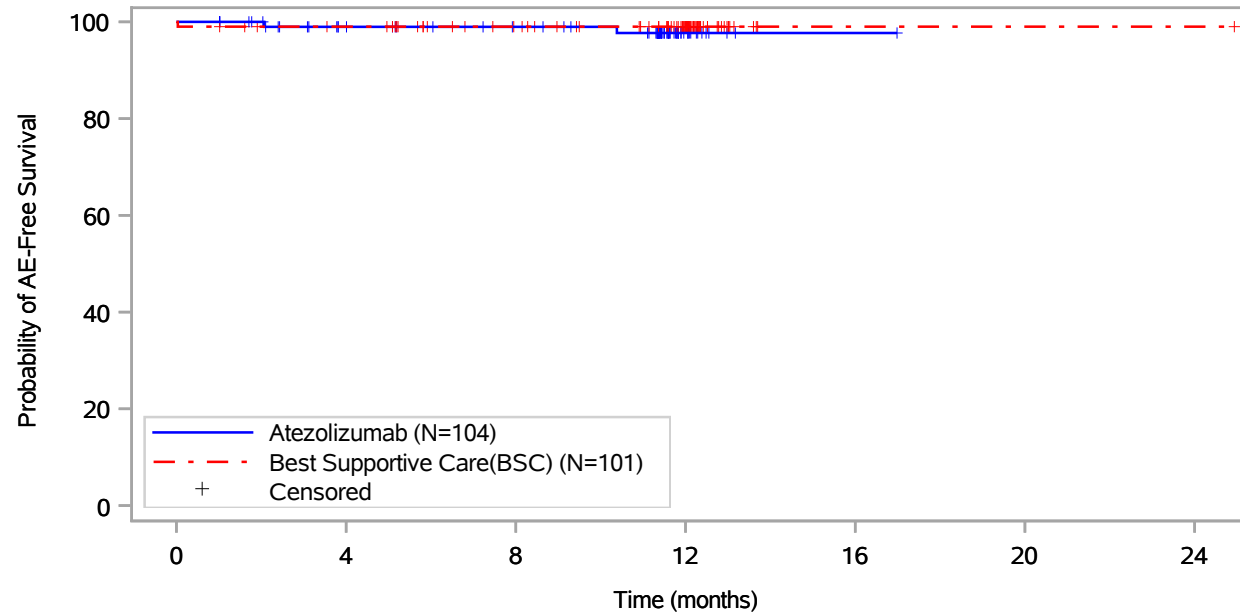
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hyperuricaemia



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

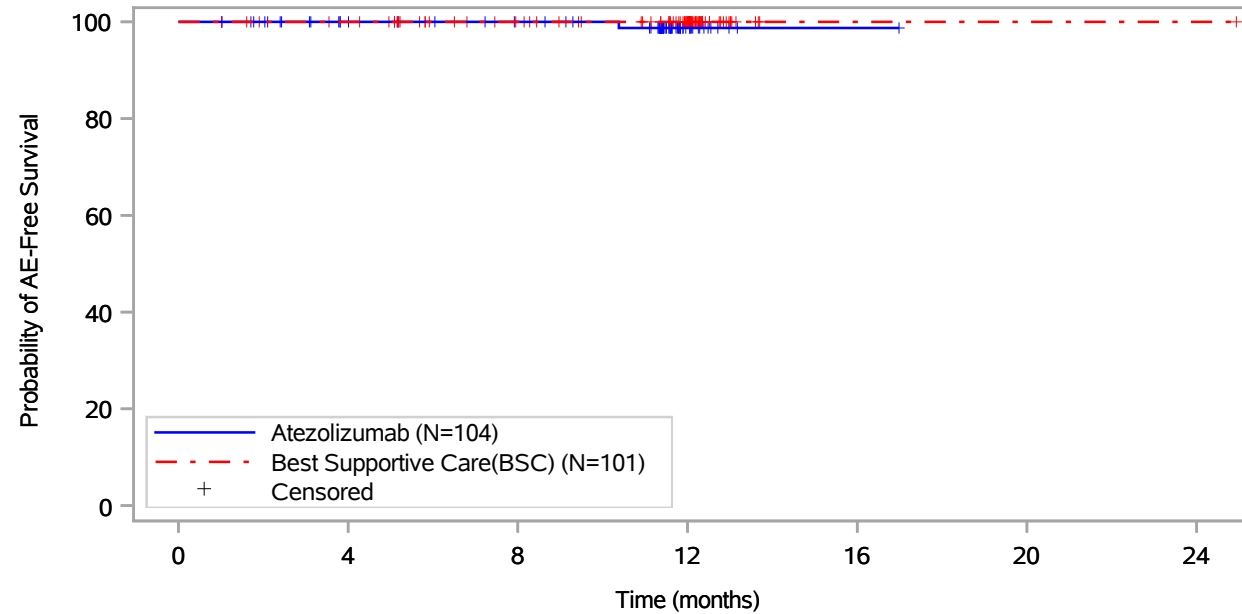
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

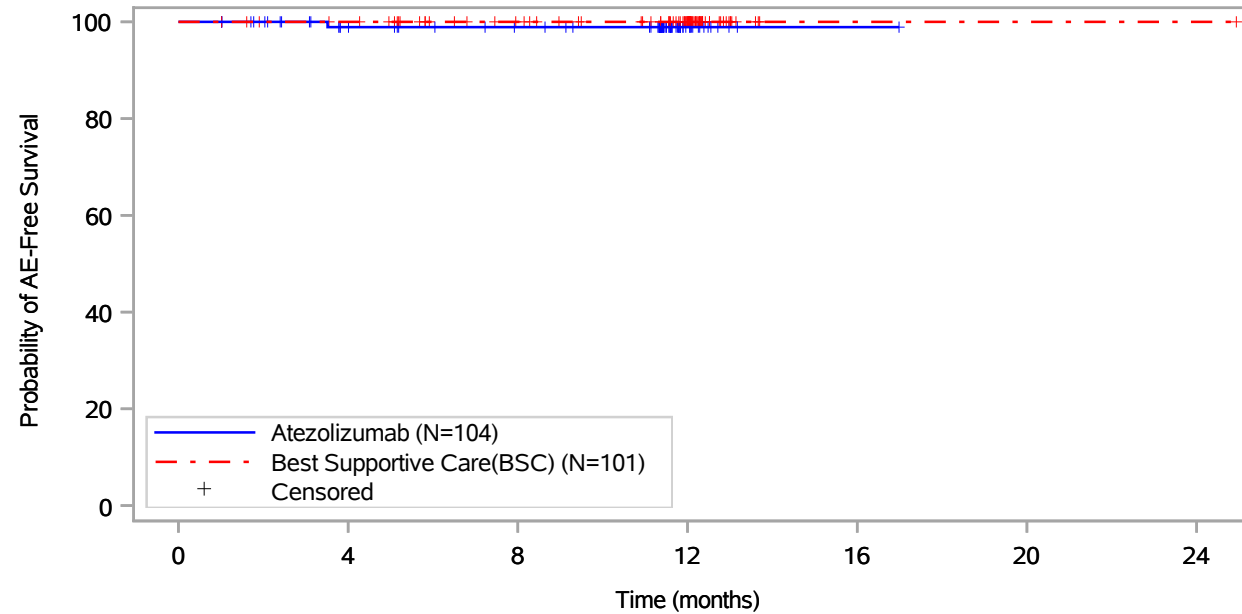
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypoglycaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

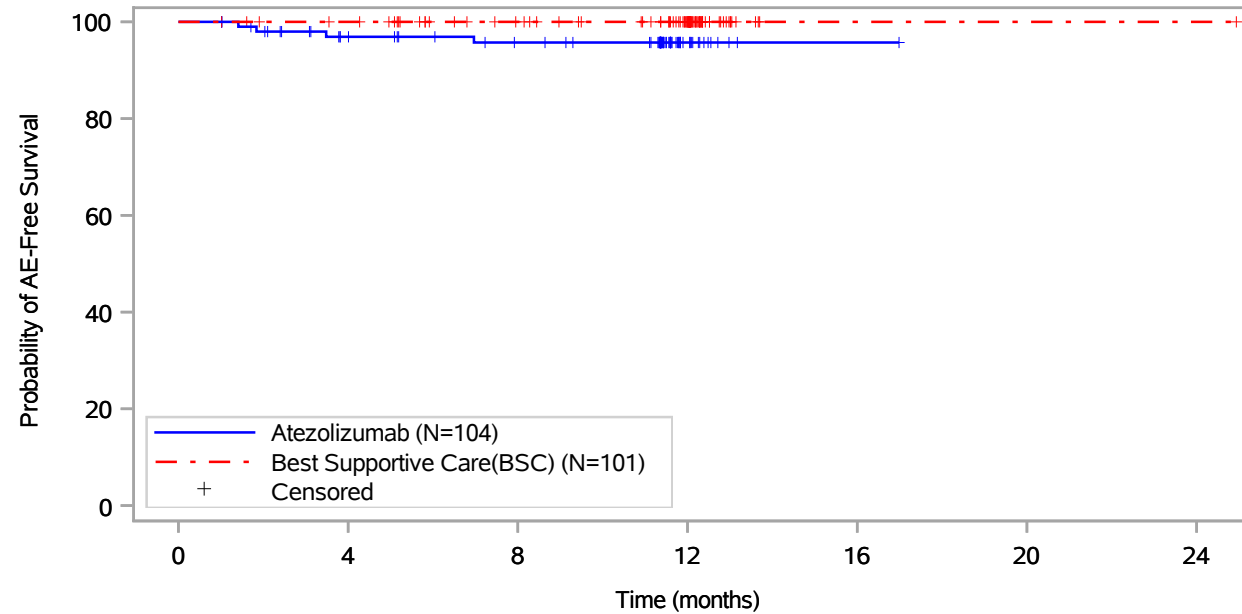
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

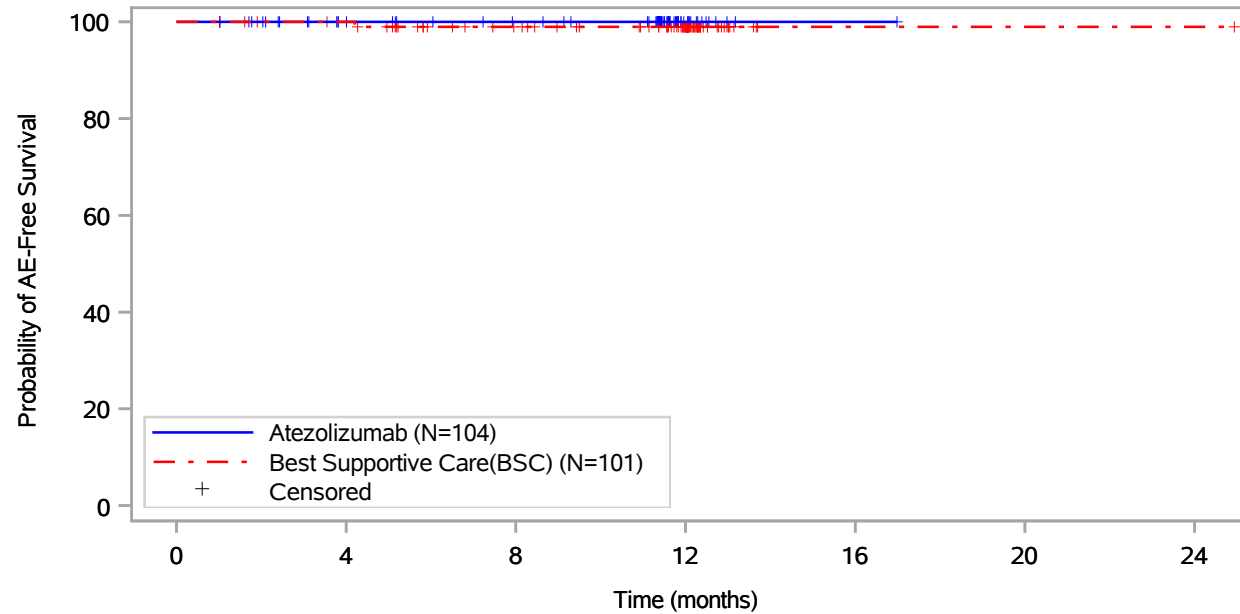
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypomagnesaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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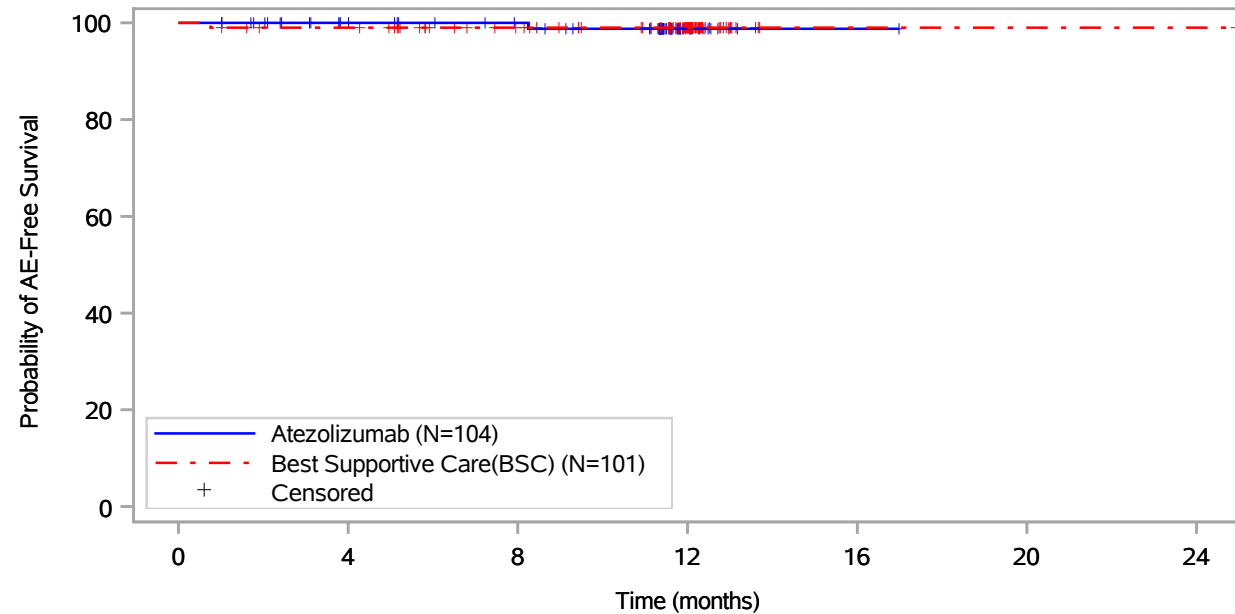
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	17	45	99	99	99

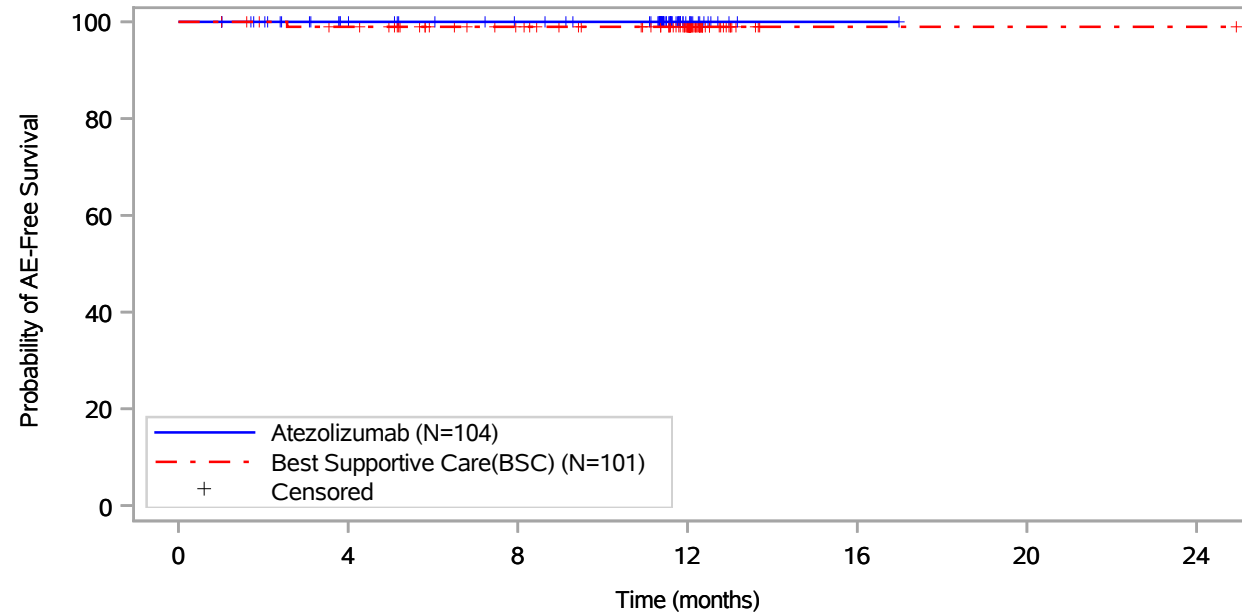
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Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypovolaemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

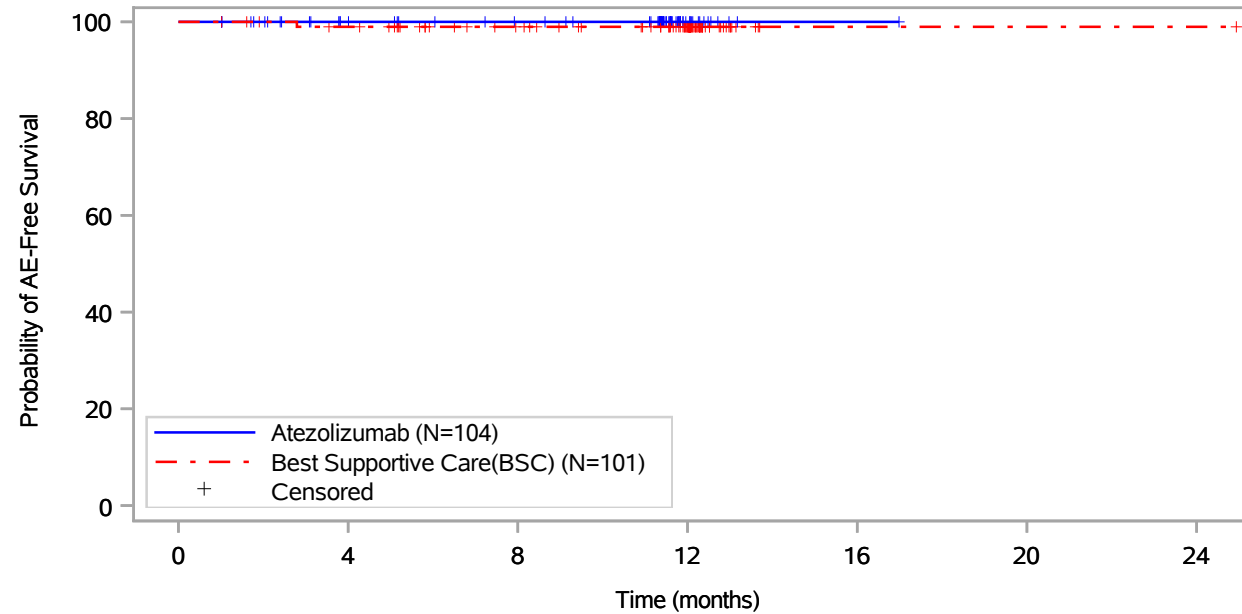
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Iron deficiency



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

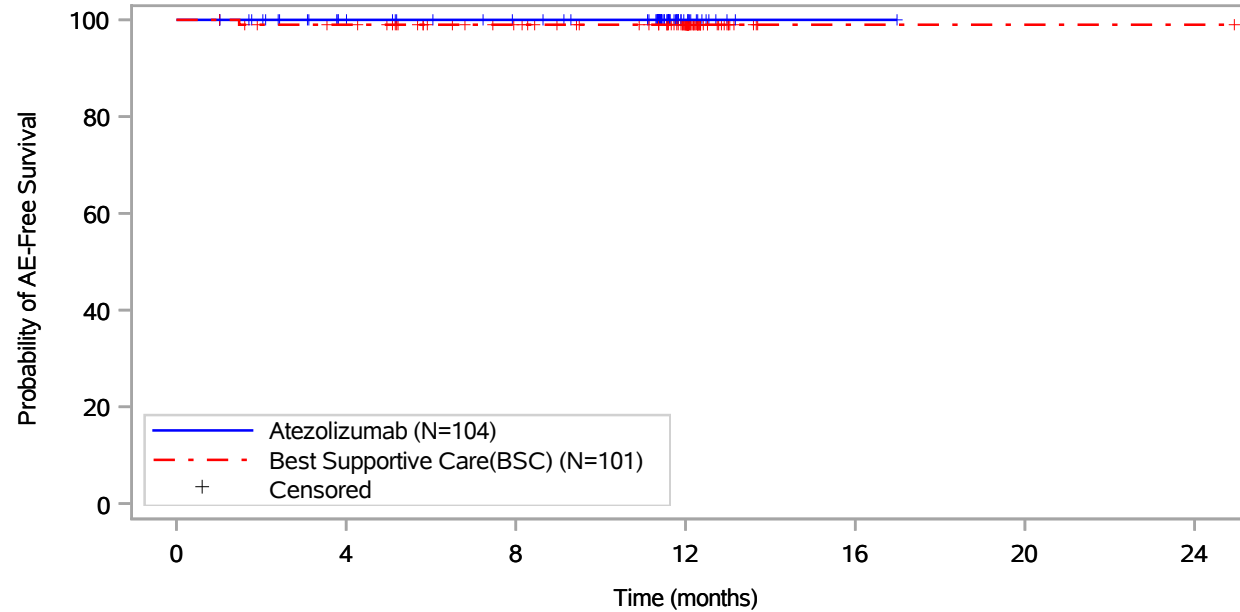
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Vitamin D deficiency



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

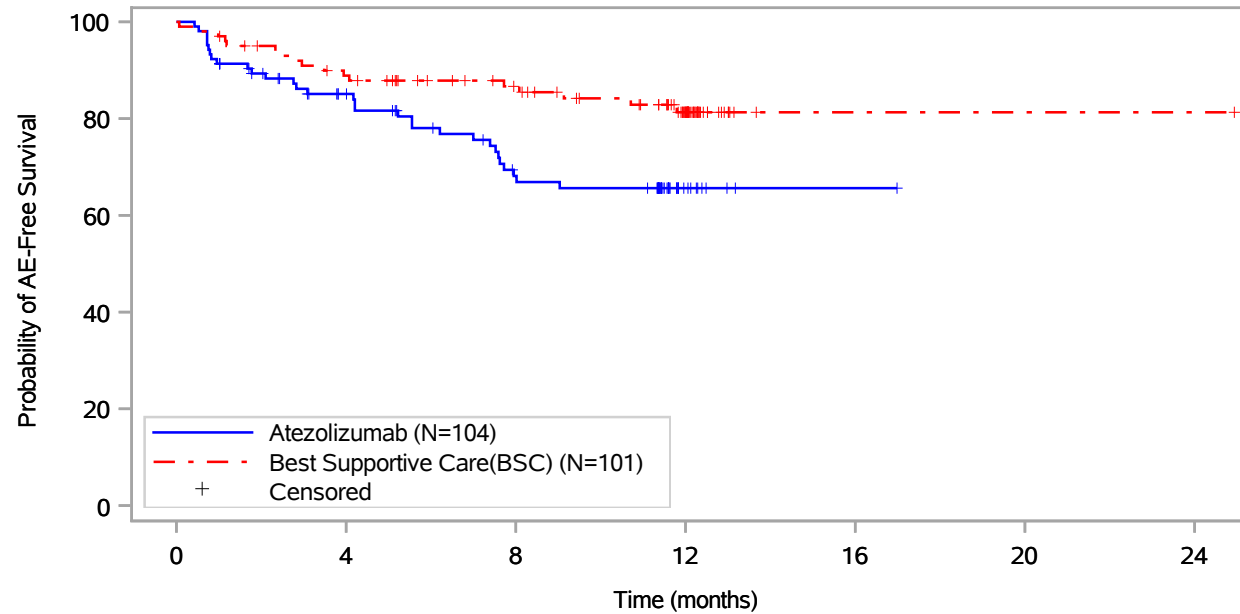
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk							
Atezolizumab (N=104)	104	75	54	9	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	86	72	42	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	64	72	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	16	42	83	83	83

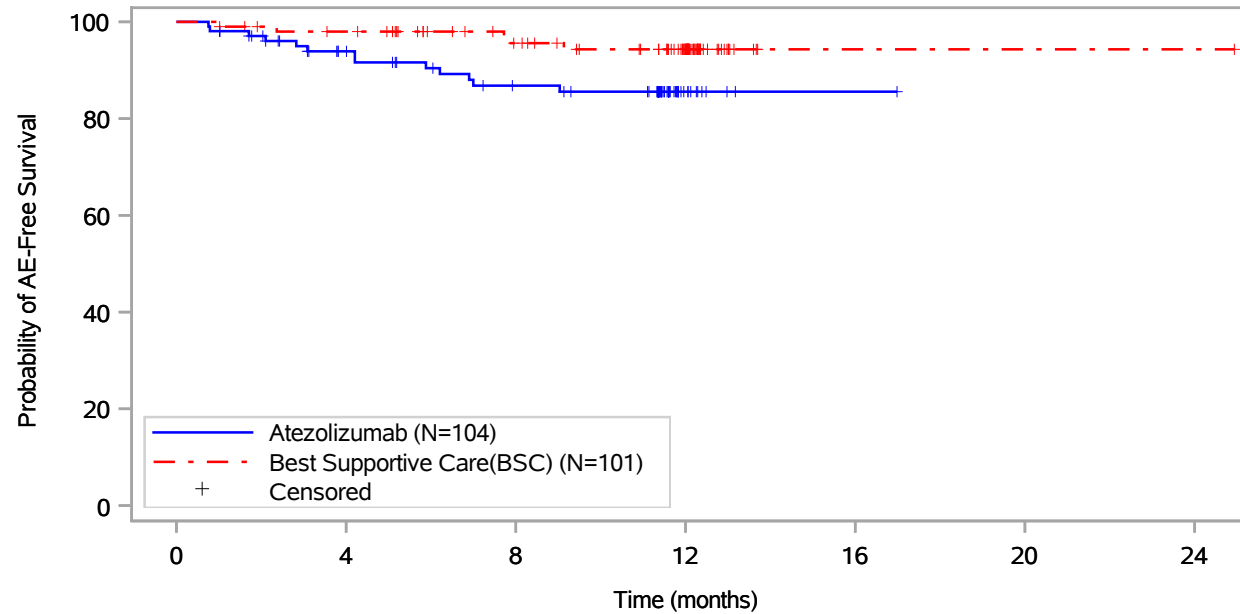
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Arthralgia



Patients at risk							
Atezolizumab (N=104)	104	83	70	10	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	79	52	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	81	90	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	95	95	95

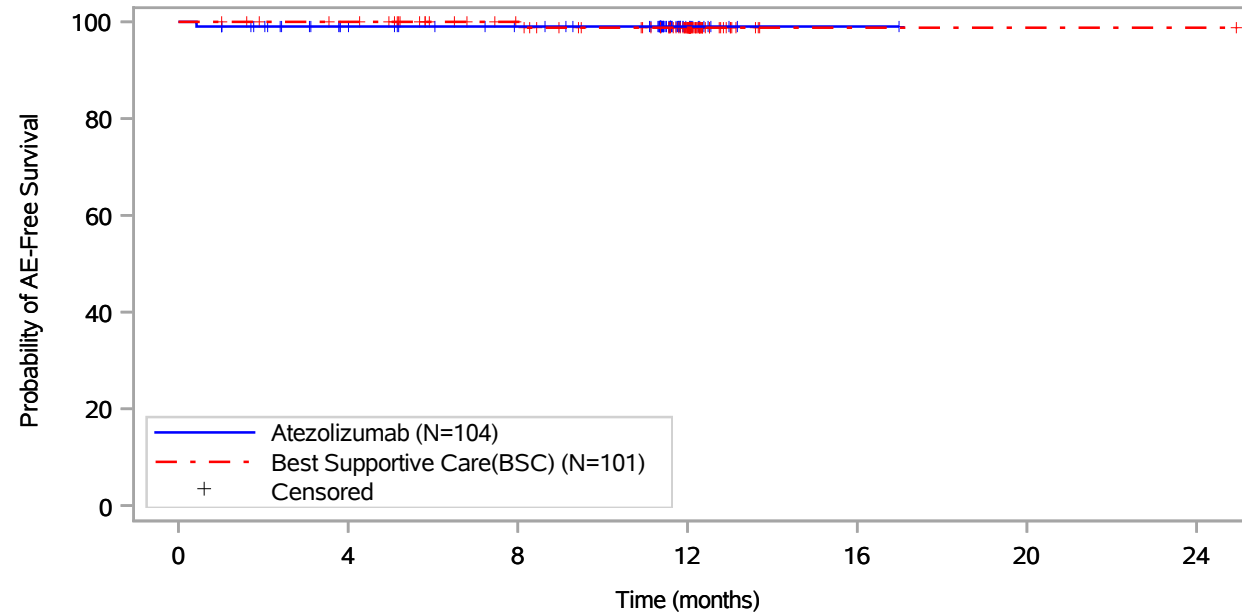
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Arthritis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

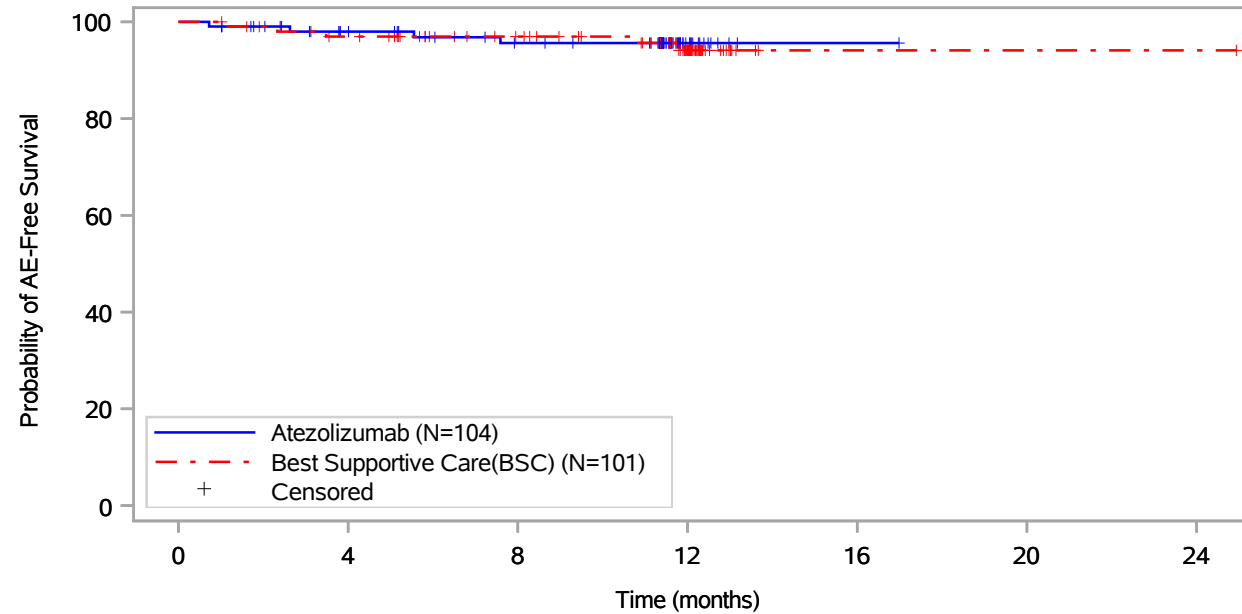
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Back pain



Patients at risk							
Atezolizumab (N=104)	104	88	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	80	50	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	95	95	95

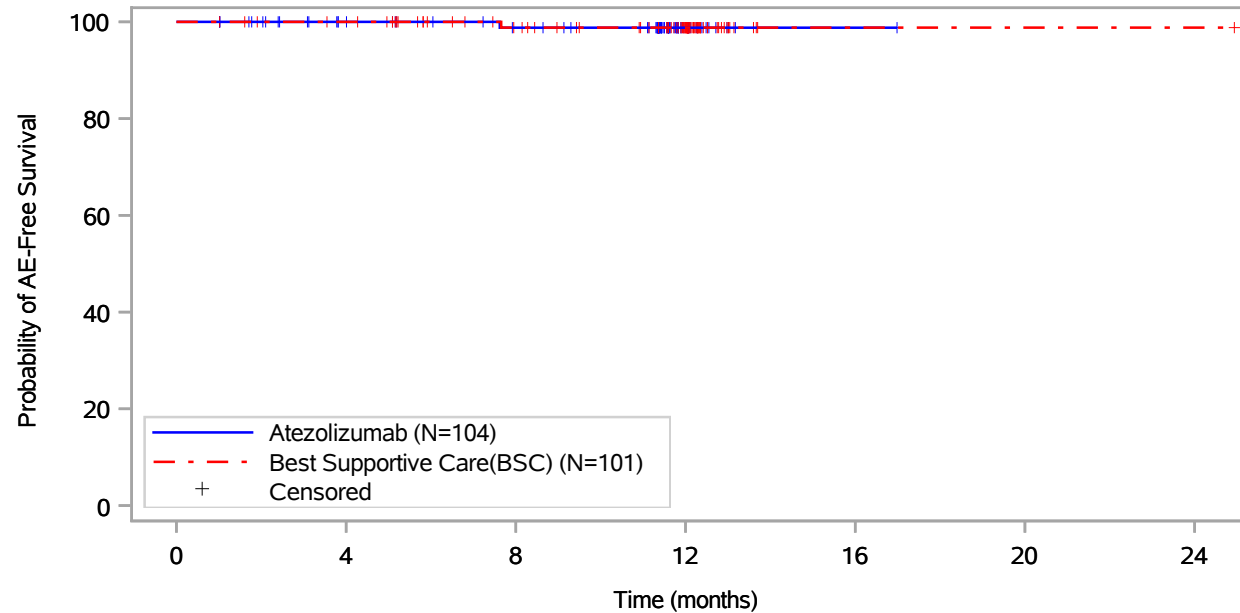
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Bone pain



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

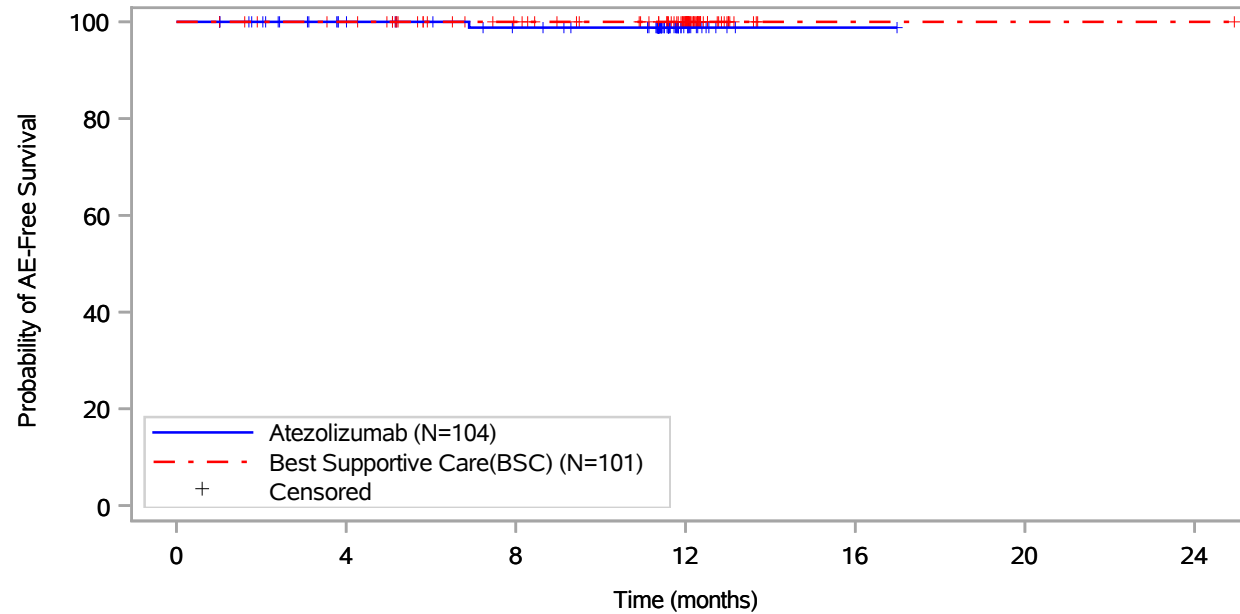
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Coccydynia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

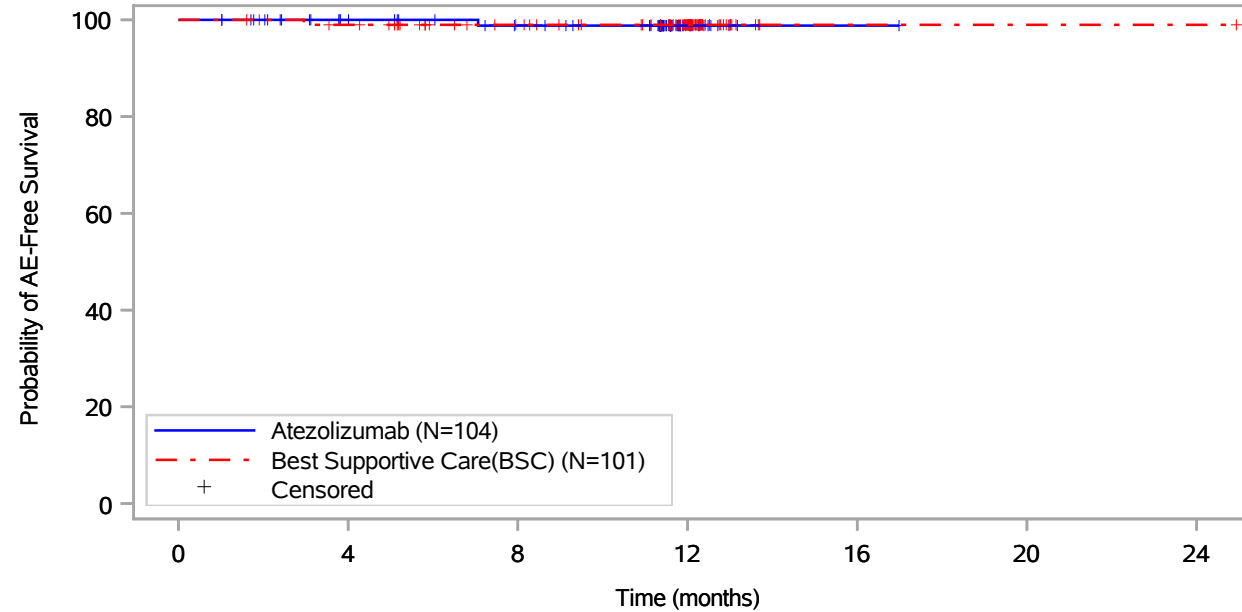
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Dupuytren's contracture



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

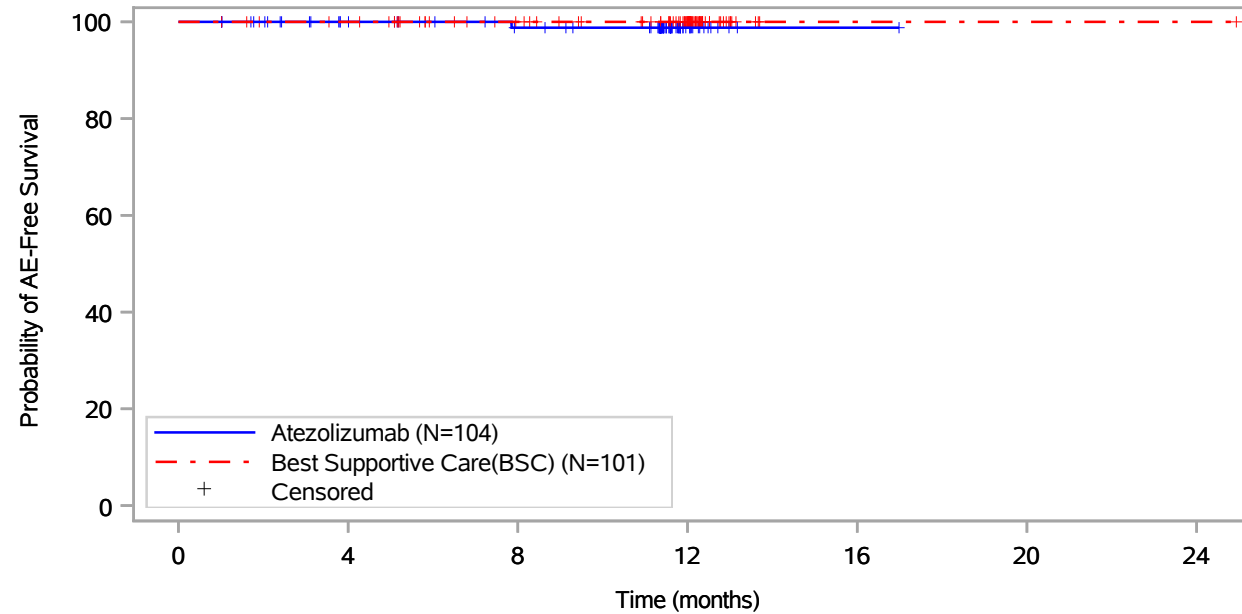
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Limb discomfort



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

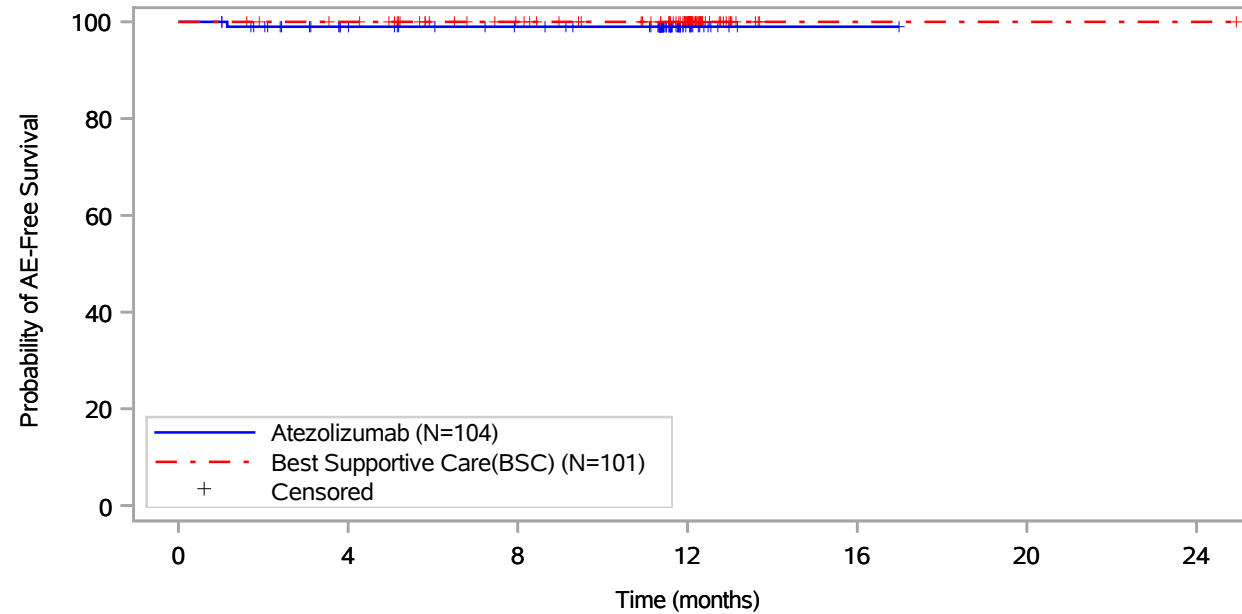
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscle fatigue



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

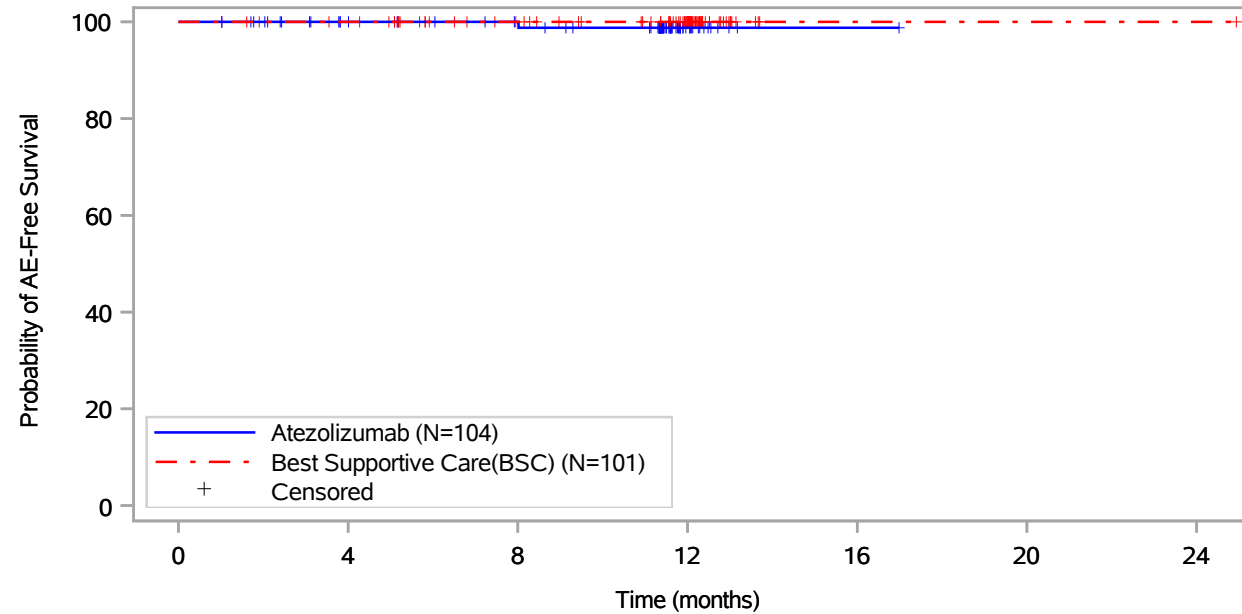
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscle spasms



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

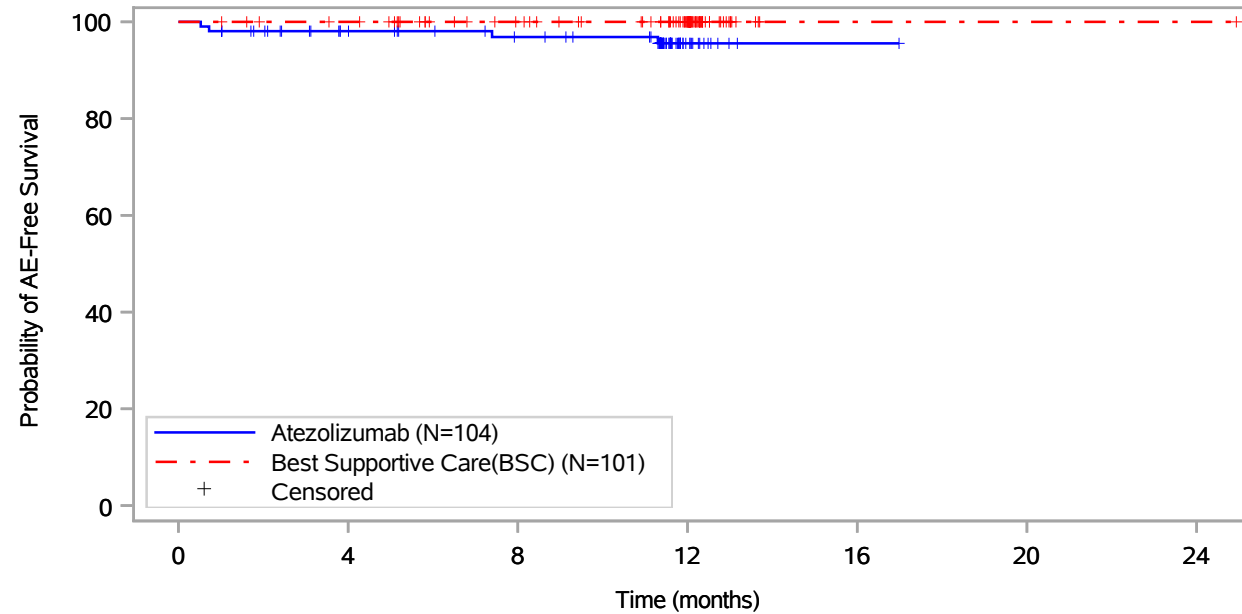
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk							
Atezolizumab (N=104)	104	87	79	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

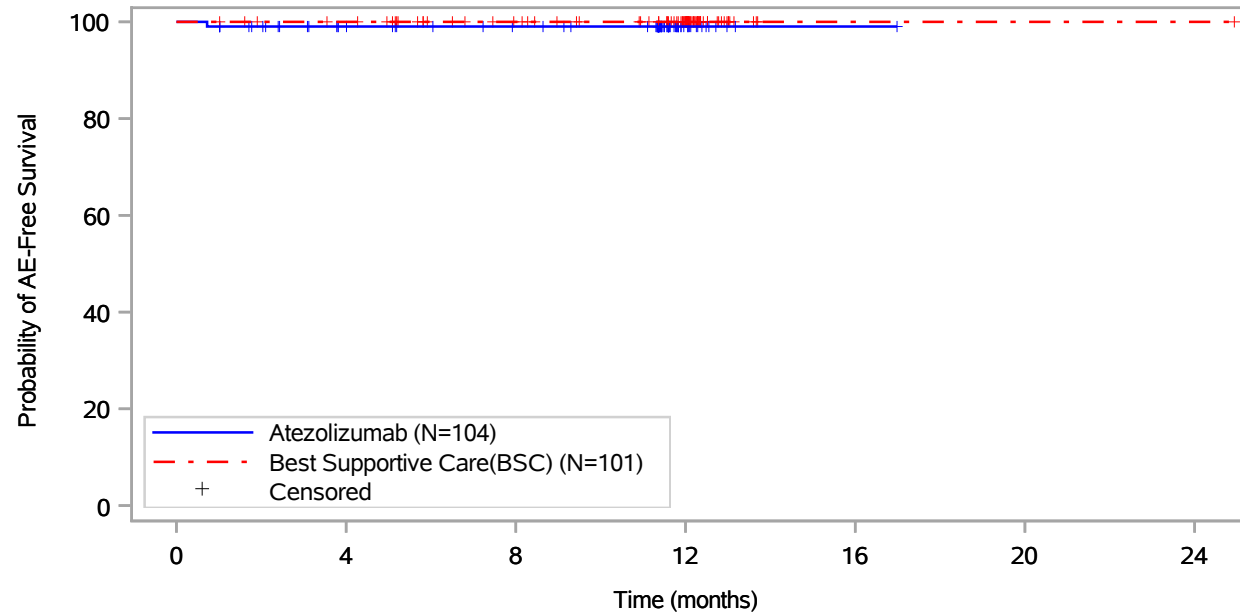
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal chest pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

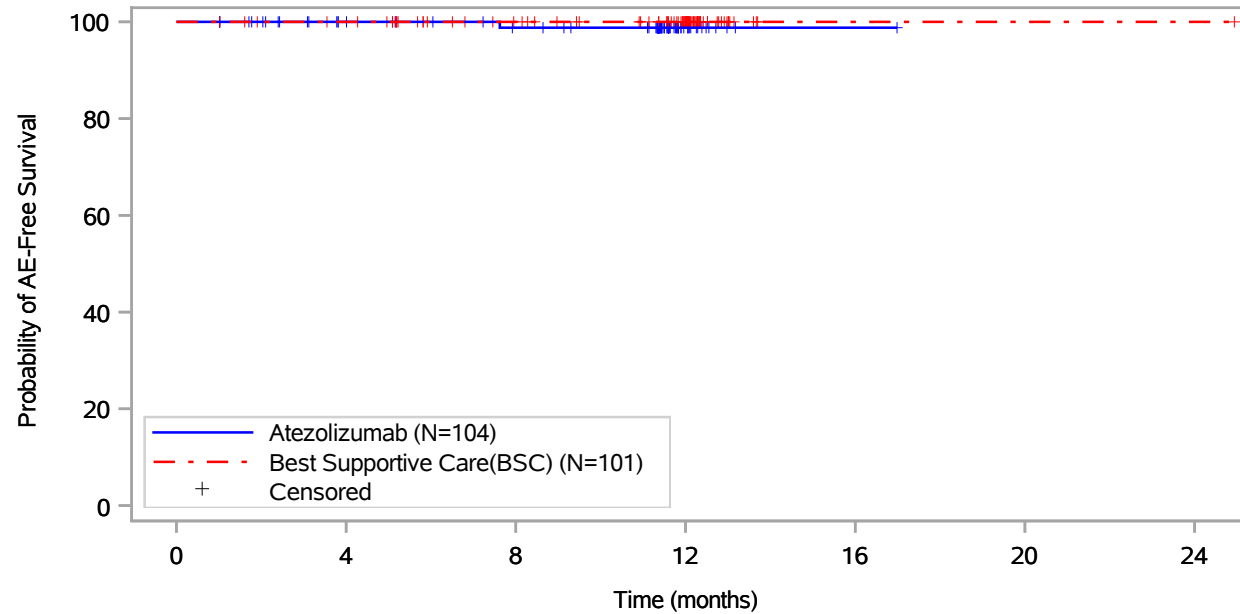
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal pain



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

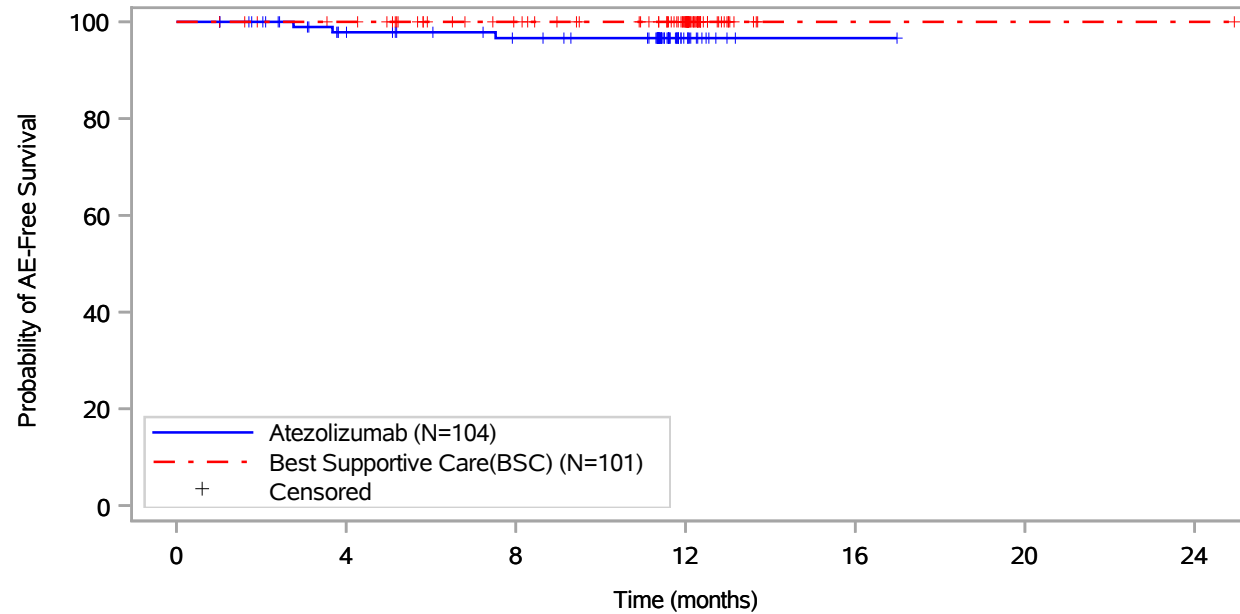
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Musculoskeletal stiffness



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	79	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	87	100	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

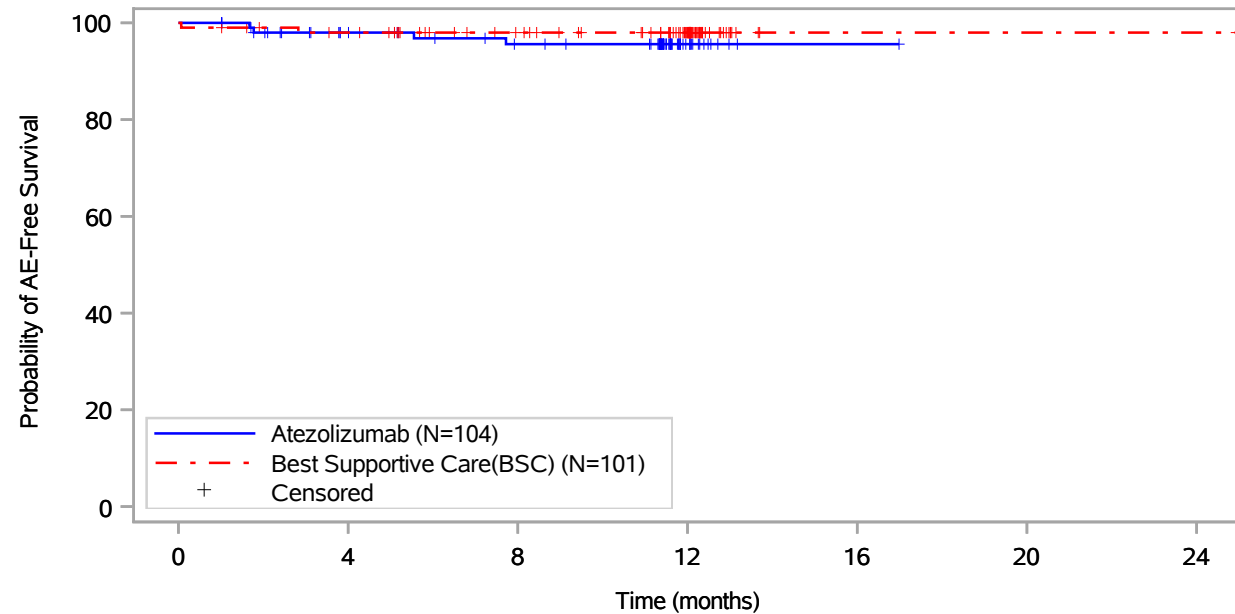
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	87	78	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	95	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	86	99	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	45	98	98	98

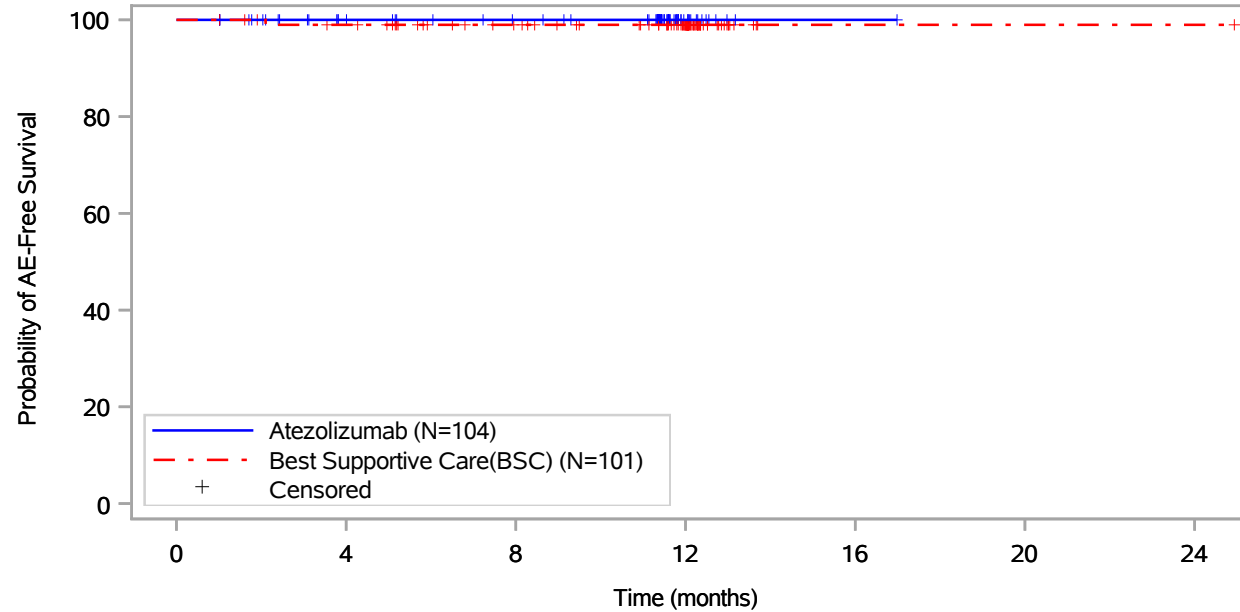
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Neck pain



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

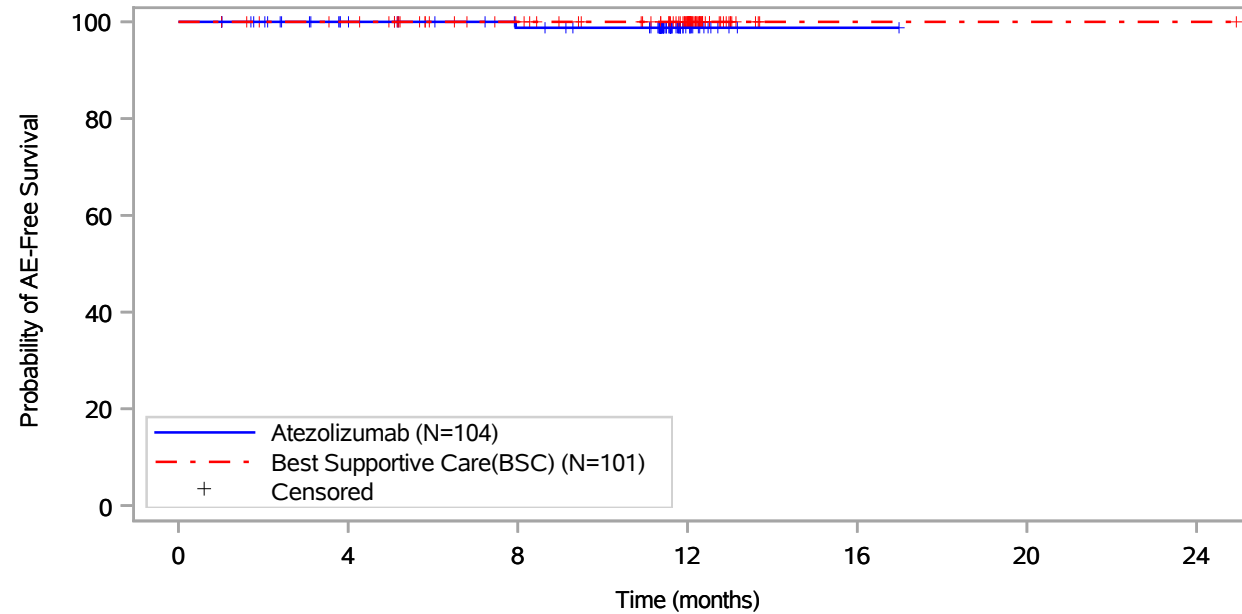
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Osteoarthritis



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

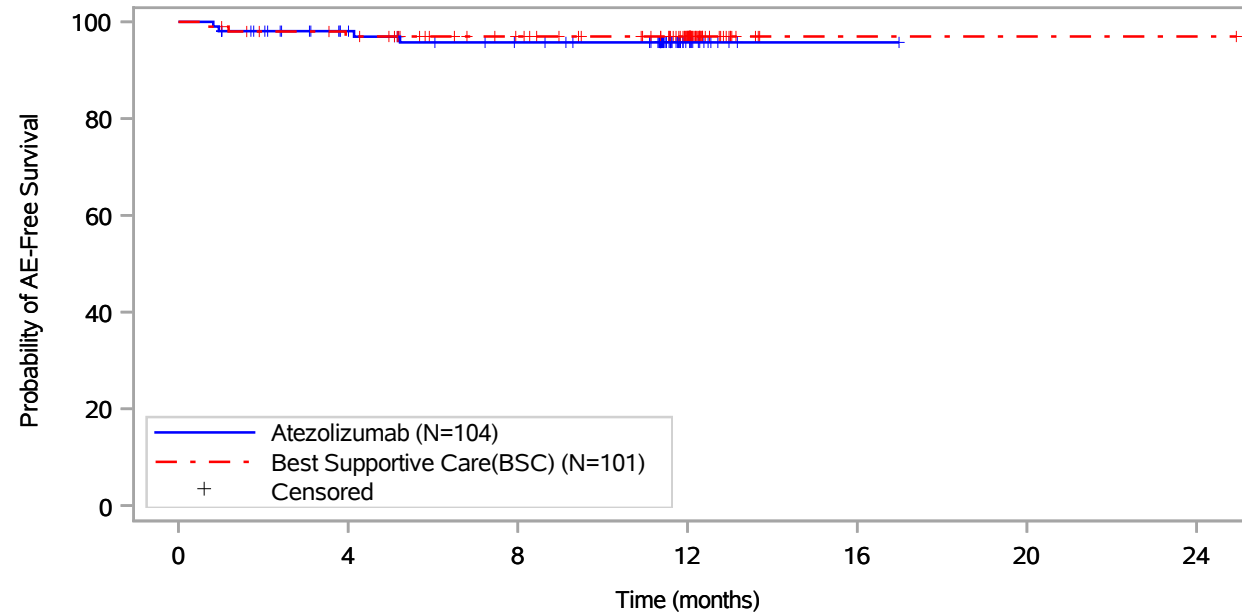
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Pain in extremity



Patients at risk							
Atezolizumab (N=104)	104	87	78	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	97	97	97

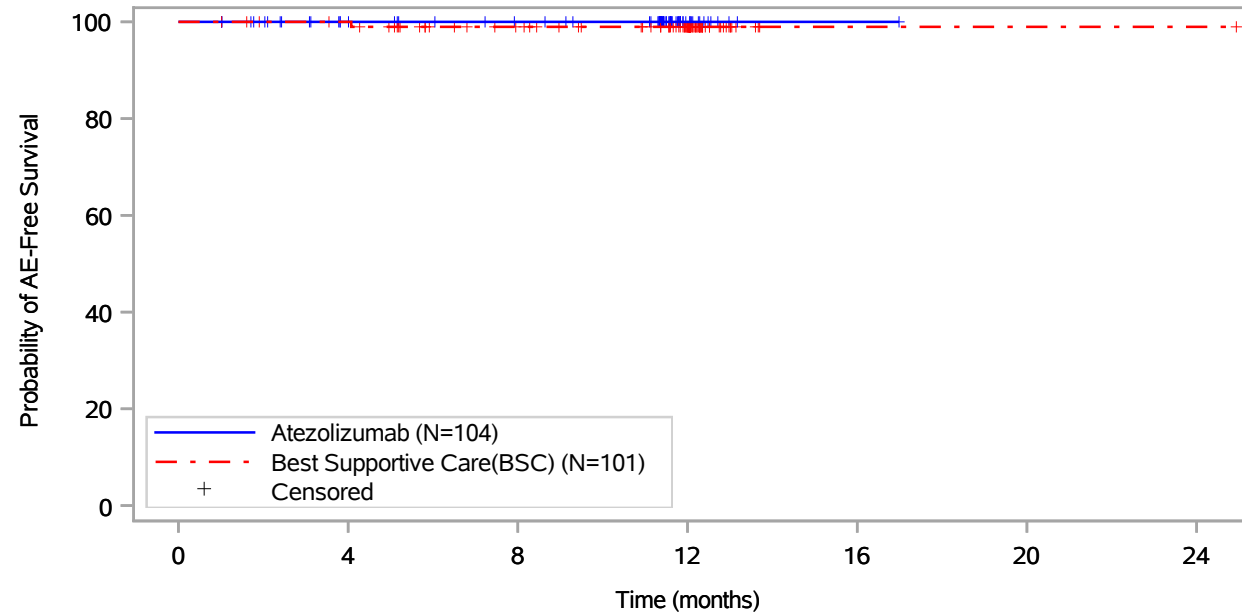
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Periarthritis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

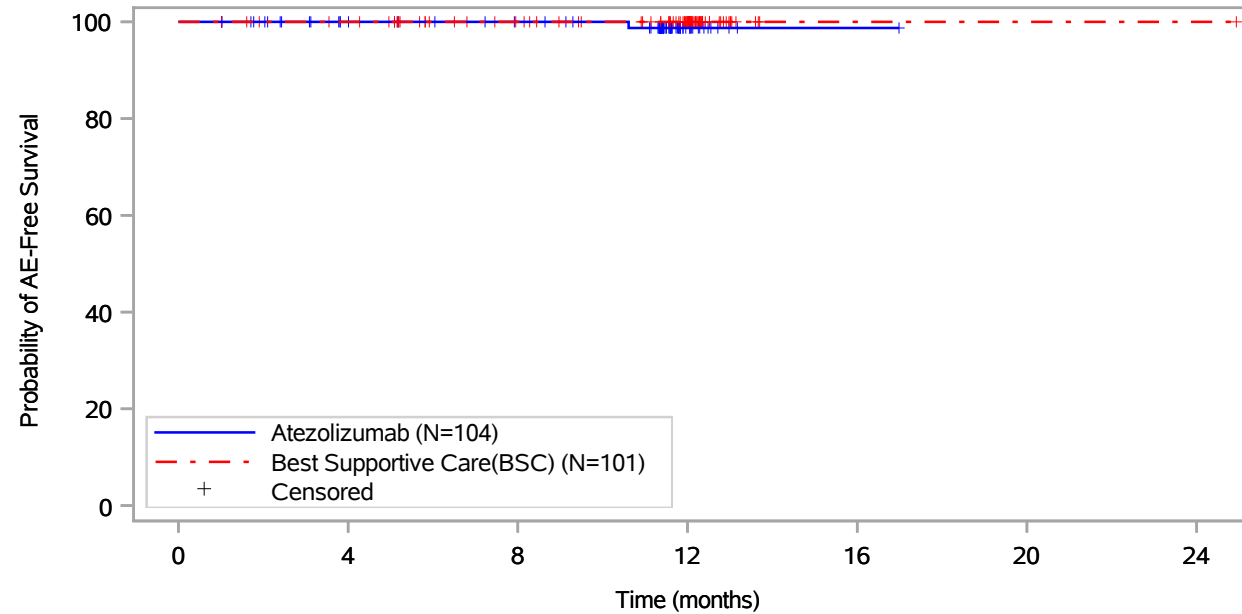
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Rotator cuff syndrome



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

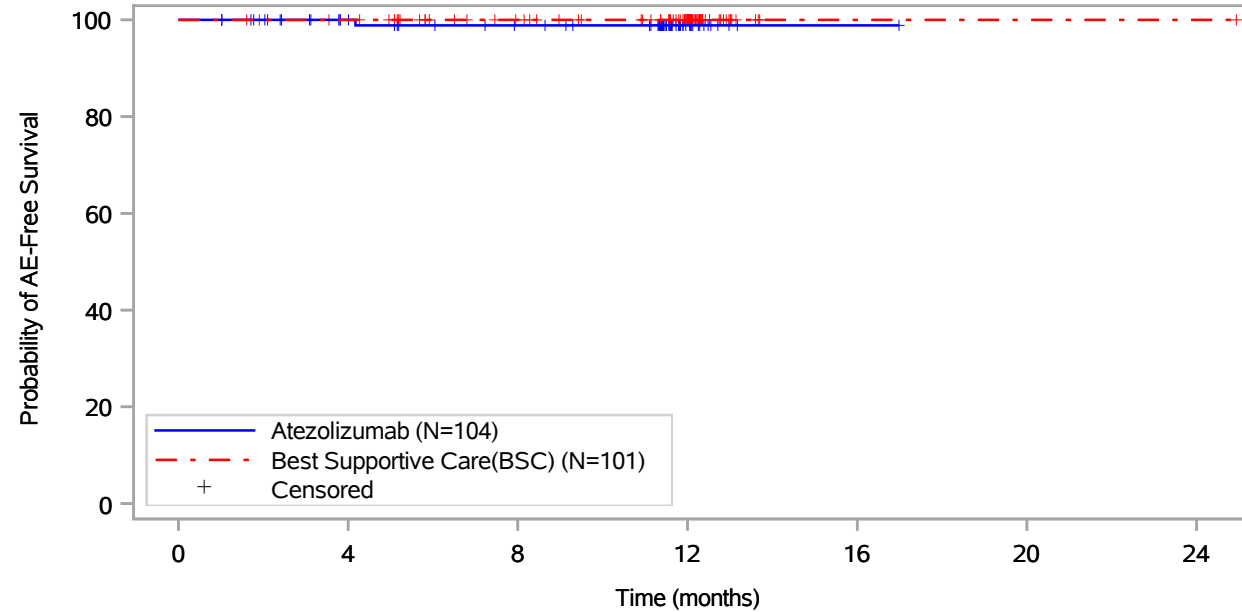
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Spinal pain



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

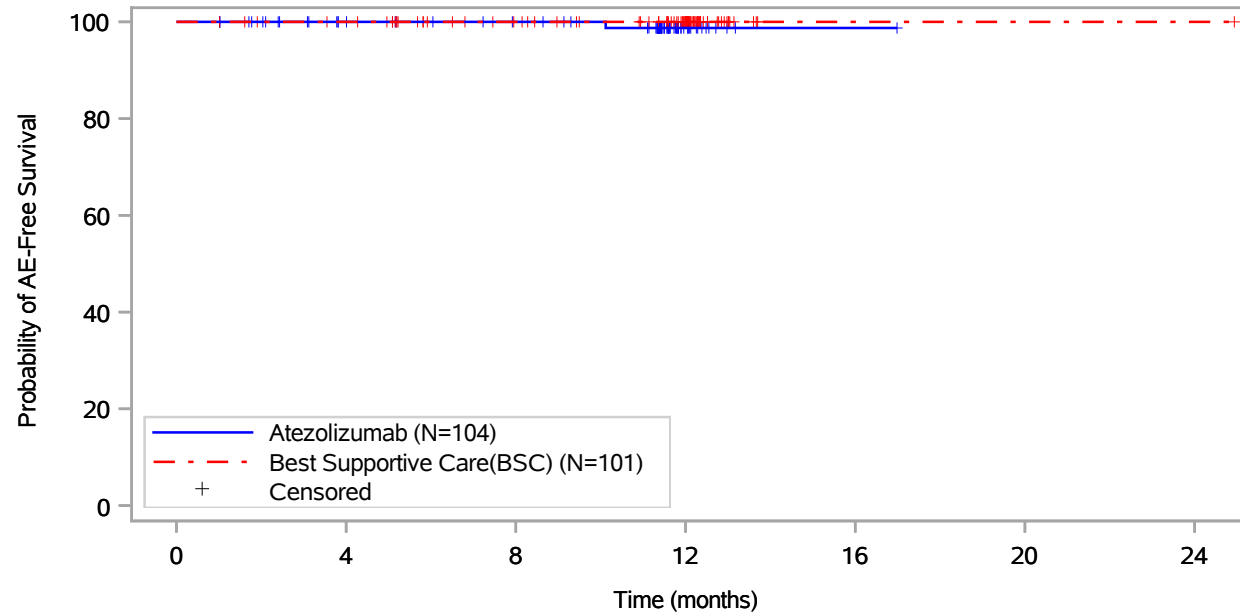
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Synovial cyst



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

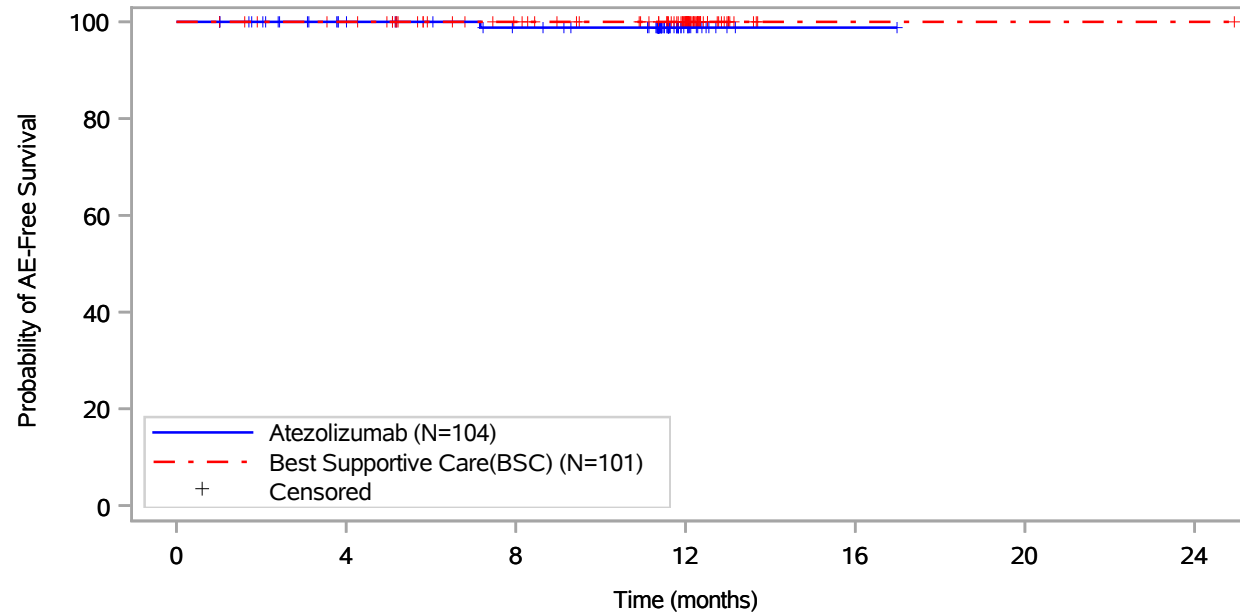
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Tendonitis



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

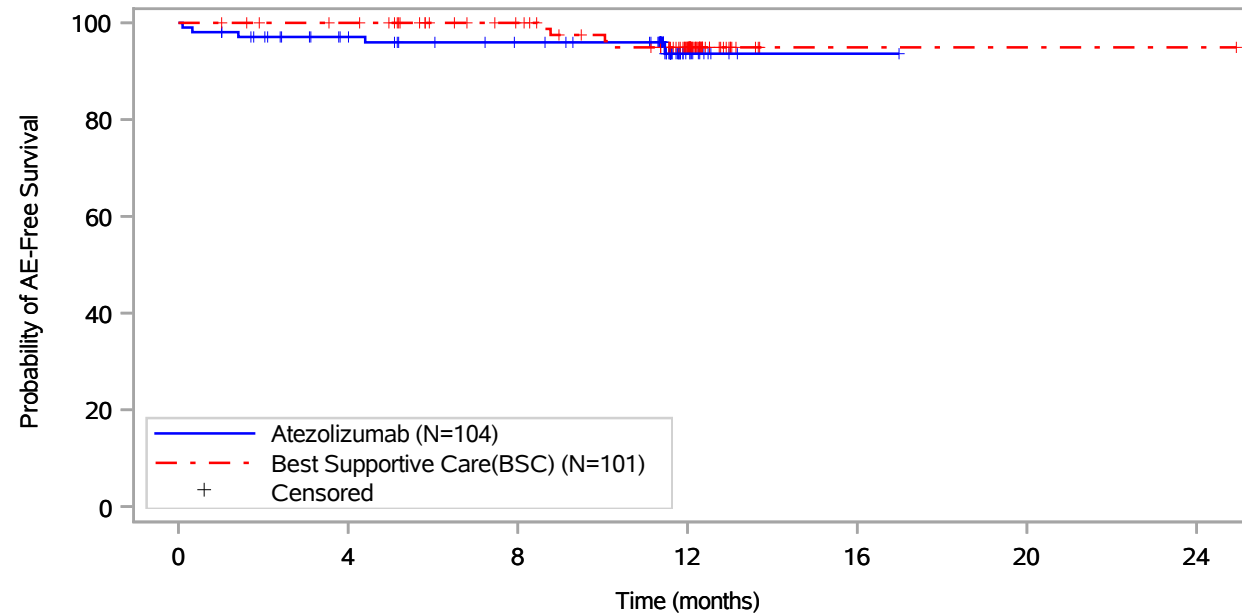
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	80	12	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	13	20	87	98	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	42	96	96	96

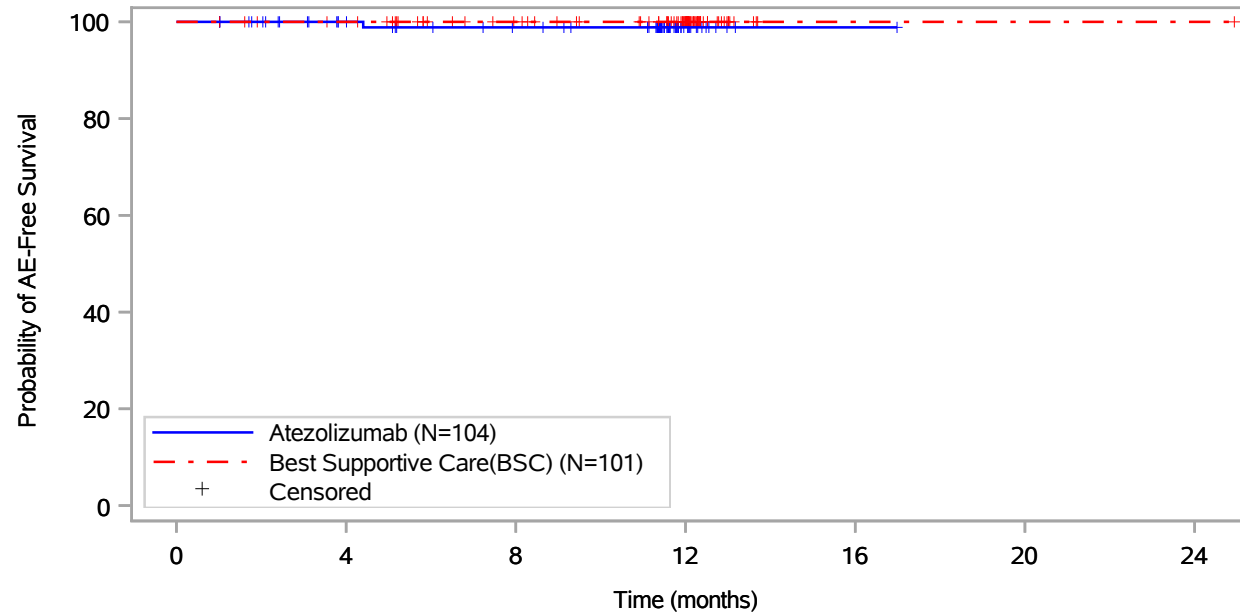
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Basal cell carcinoma



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

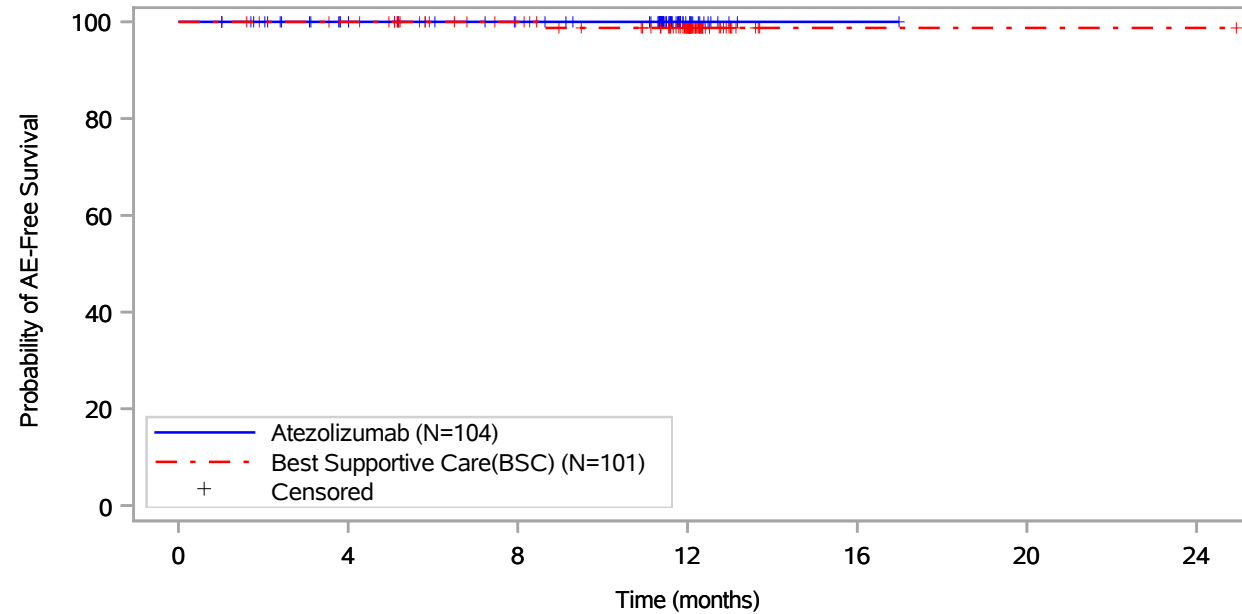
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Breast cancer



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99	99

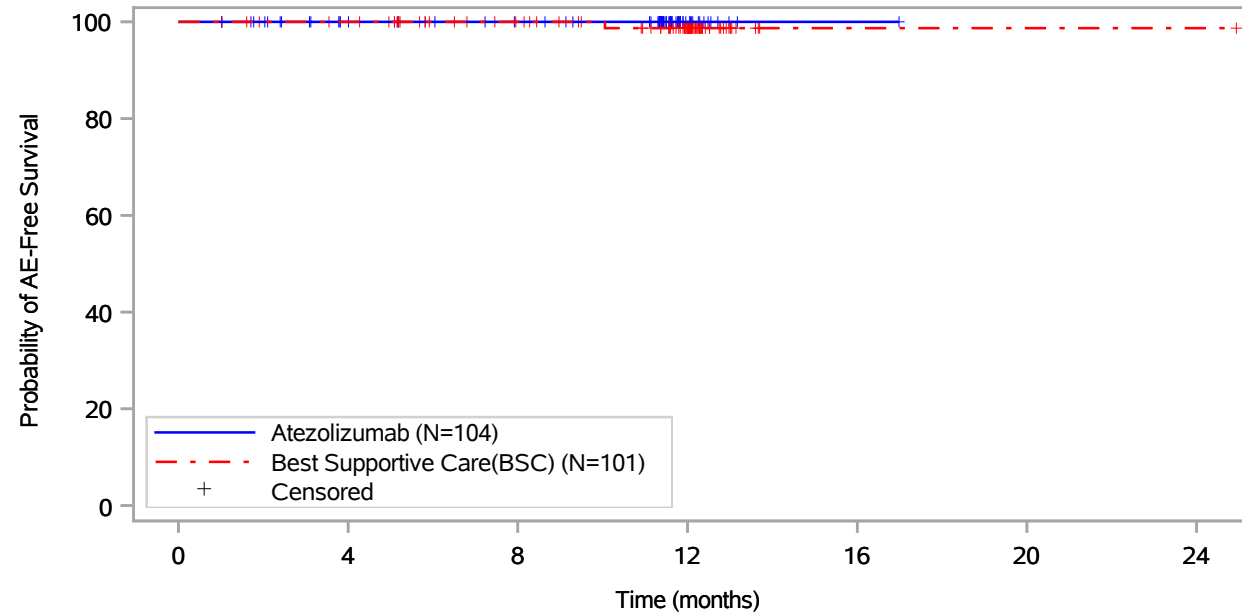
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Fibroma



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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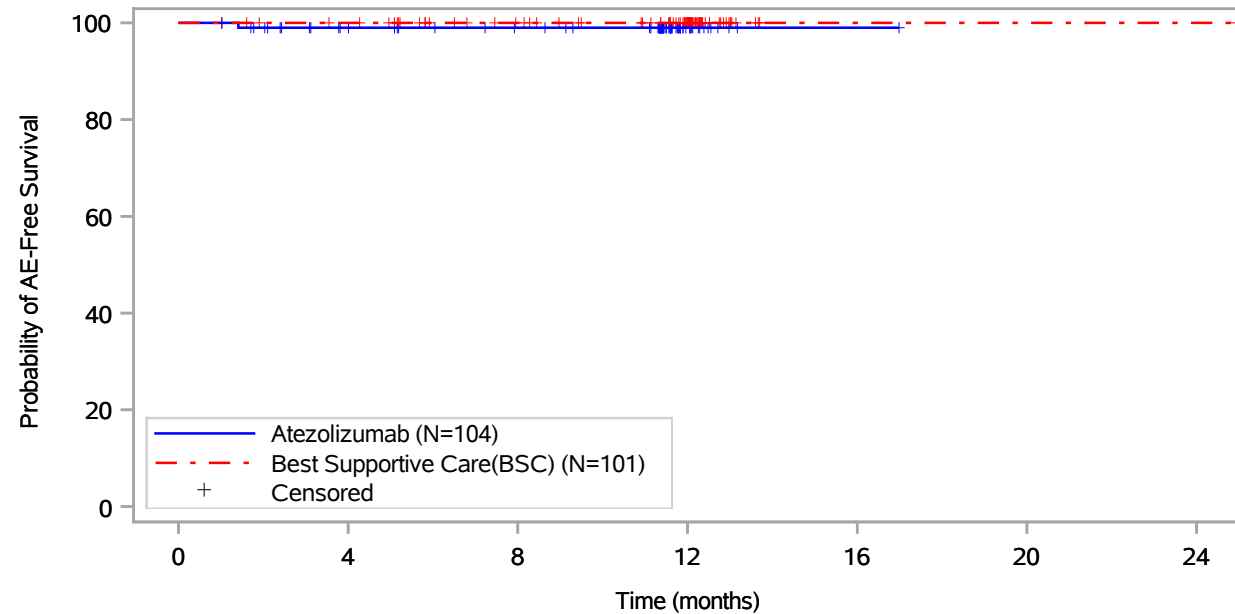
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Histiocytosis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

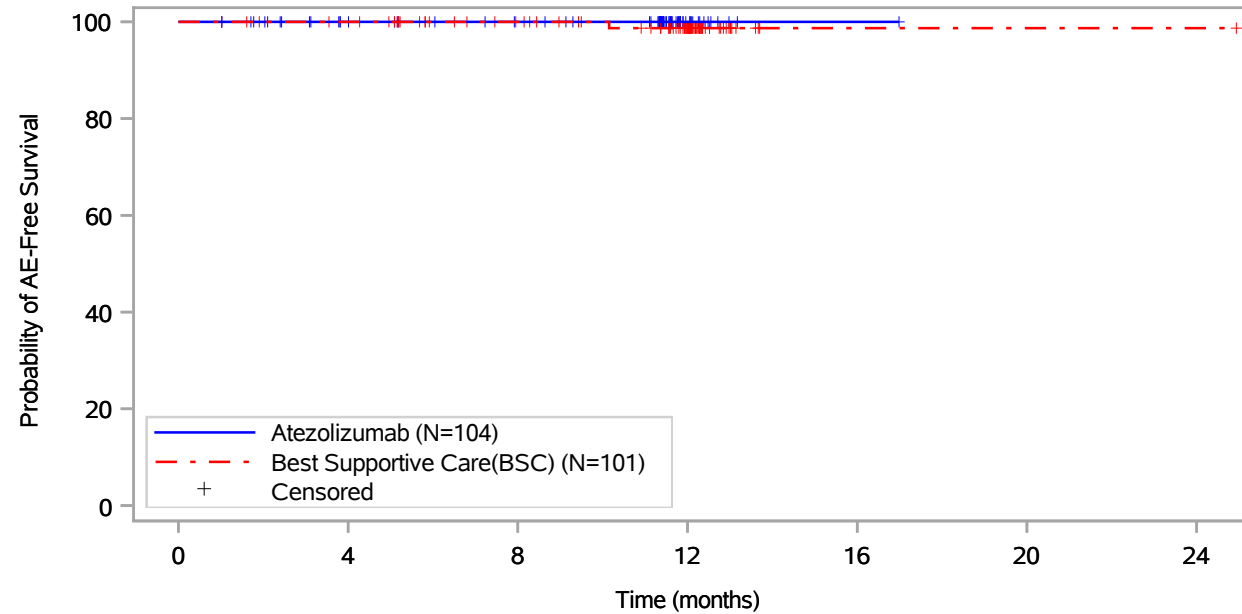
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Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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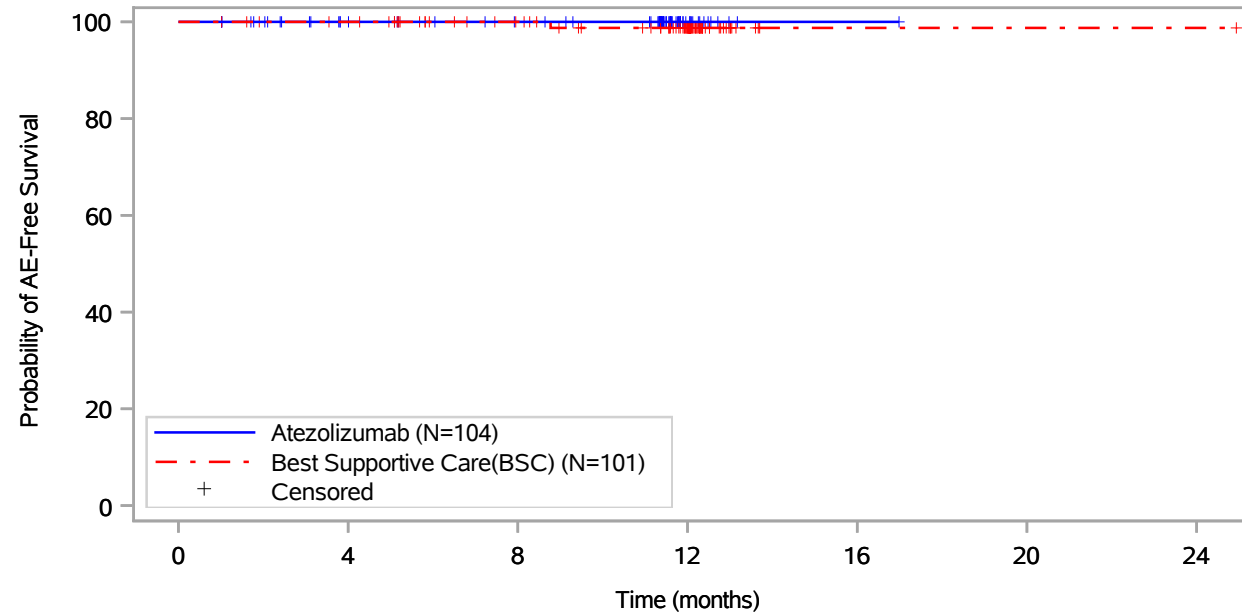
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Adverse Event

STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Prostate cancer



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

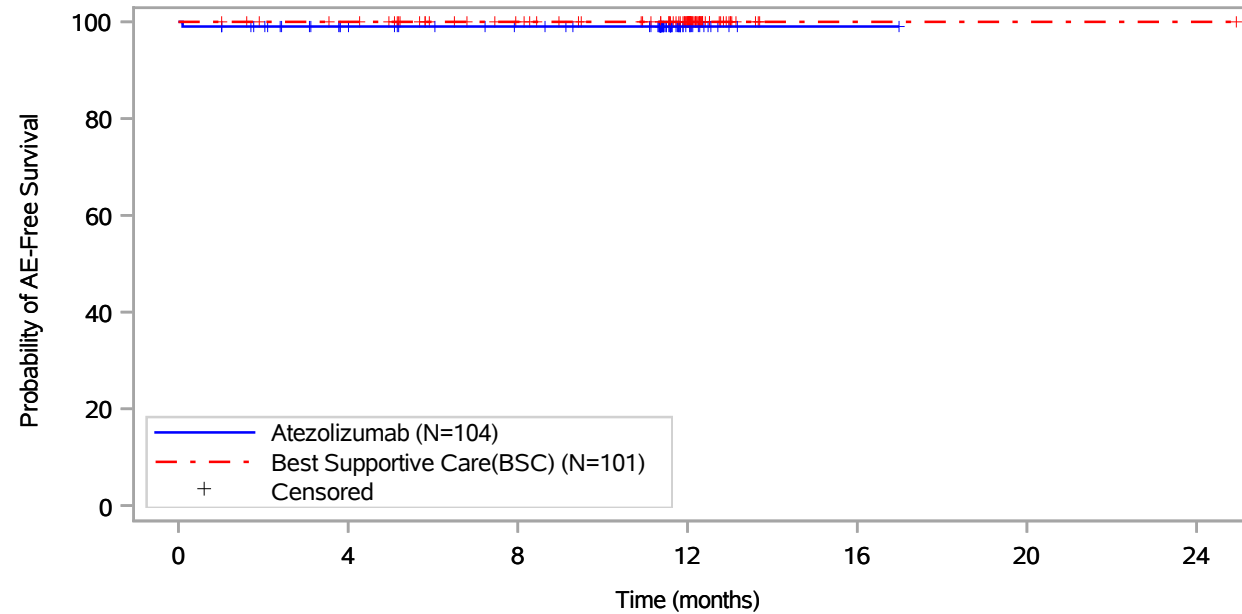
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Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

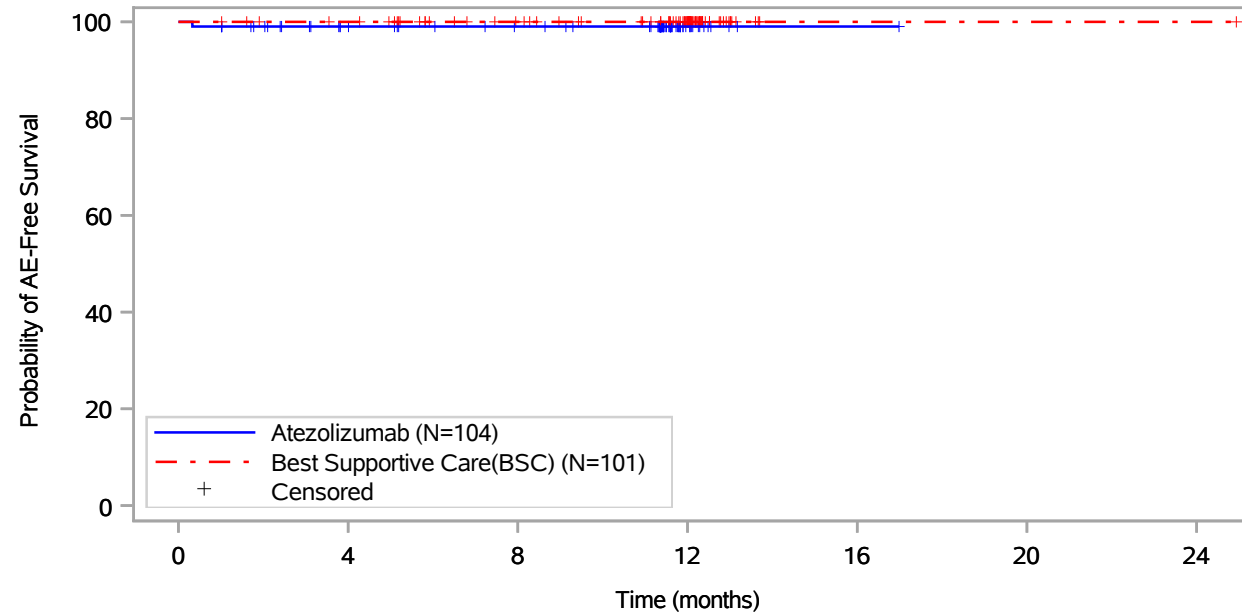
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Seborrhoeic keratosis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

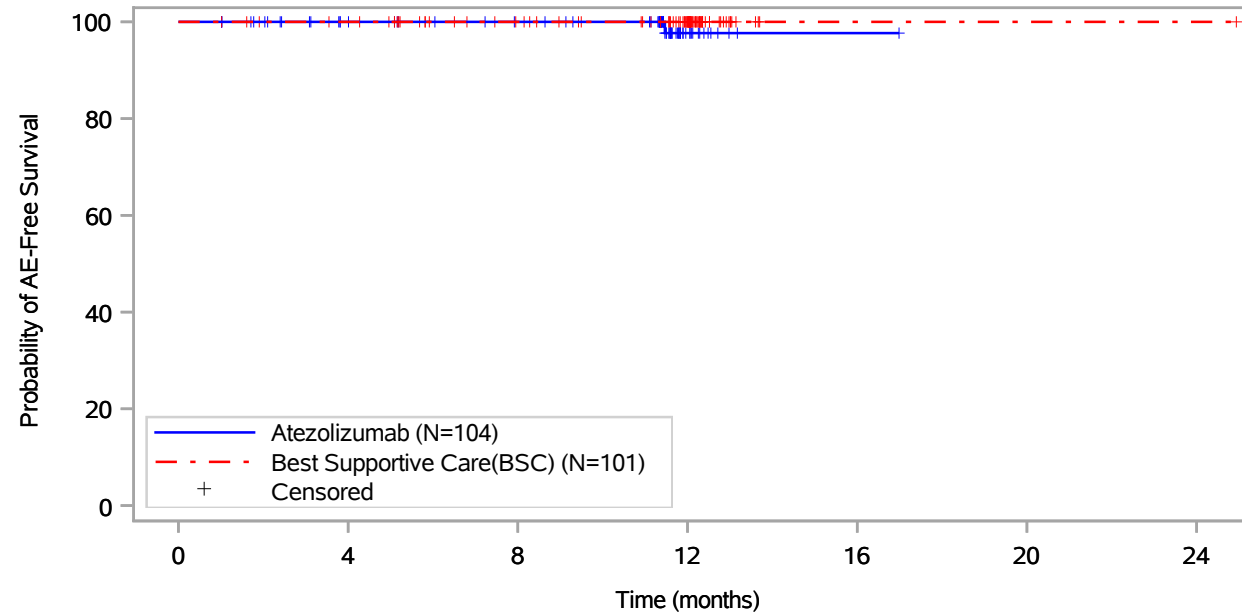
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



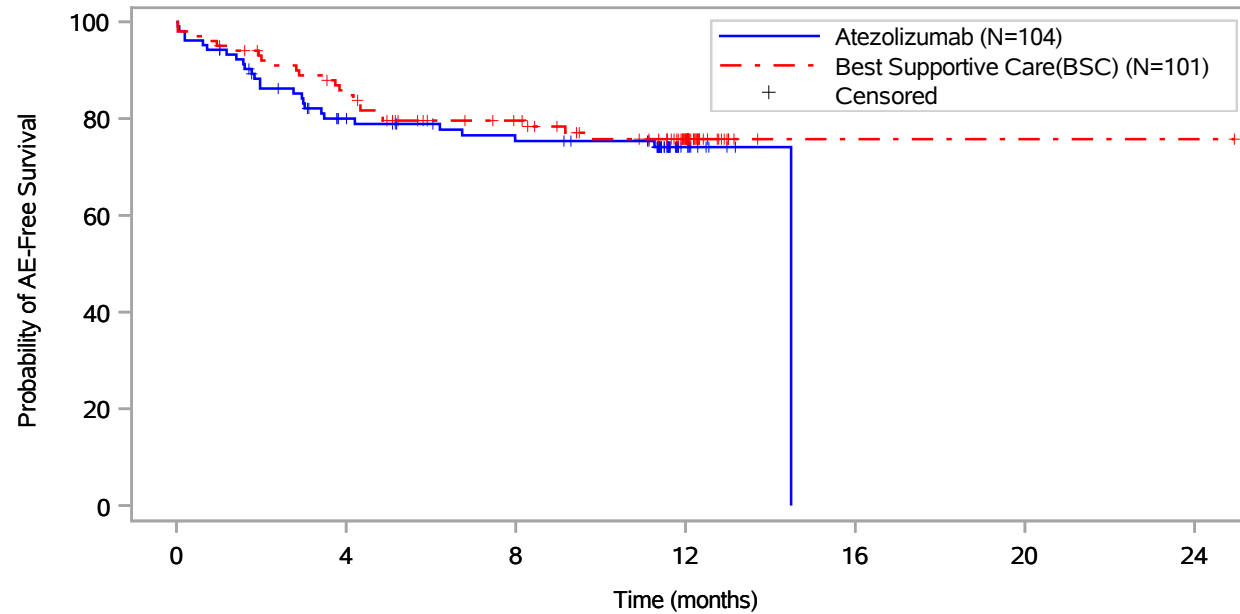
Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, All



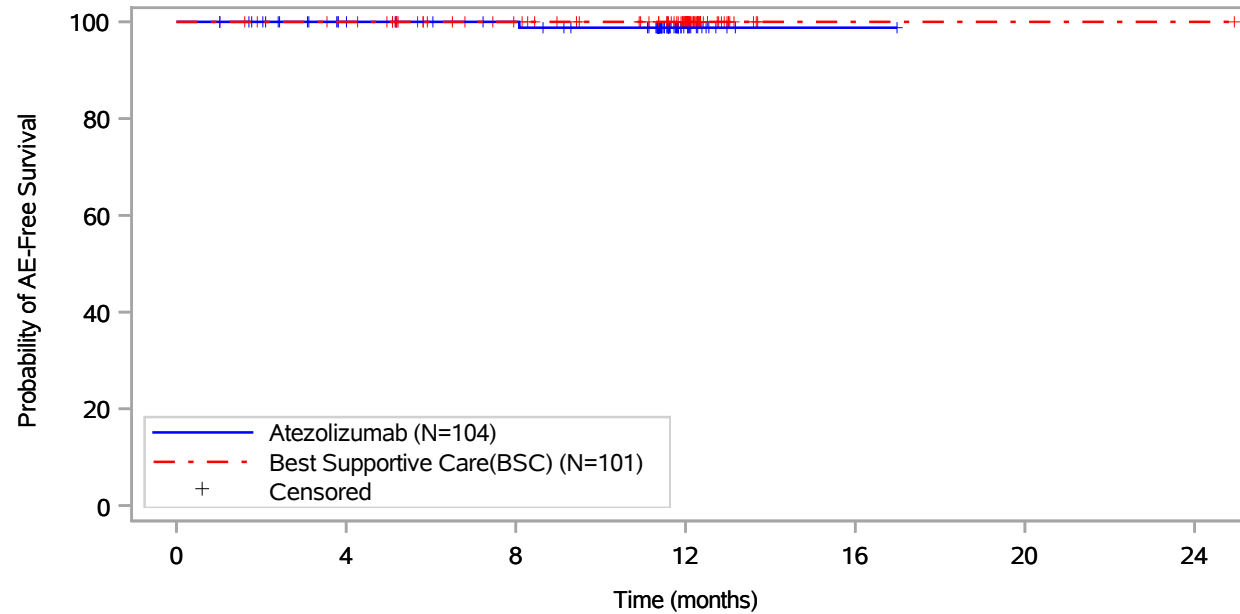
Patients at risk							
Atezolizumab (N=104)	104	73	64	10	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	82	66	39	1	1	1
Patients censored							
Atezolizumab (N=104)	0	11	16	69	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	15	39	77	77	77

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Arachnoid cyst



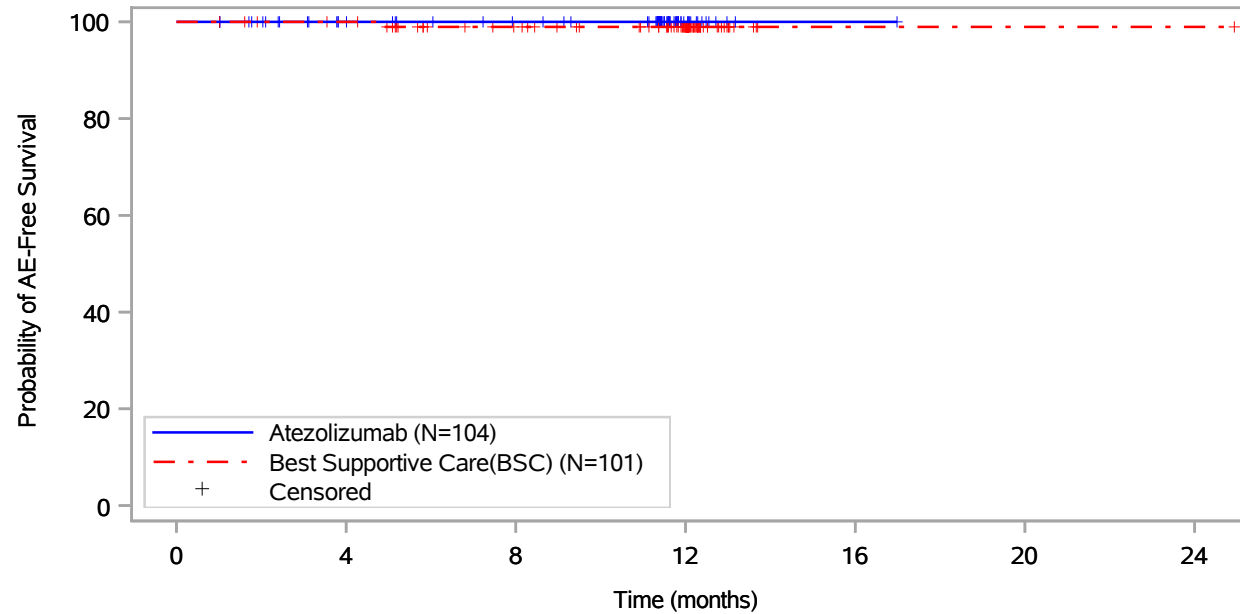
Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Brain oedema



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

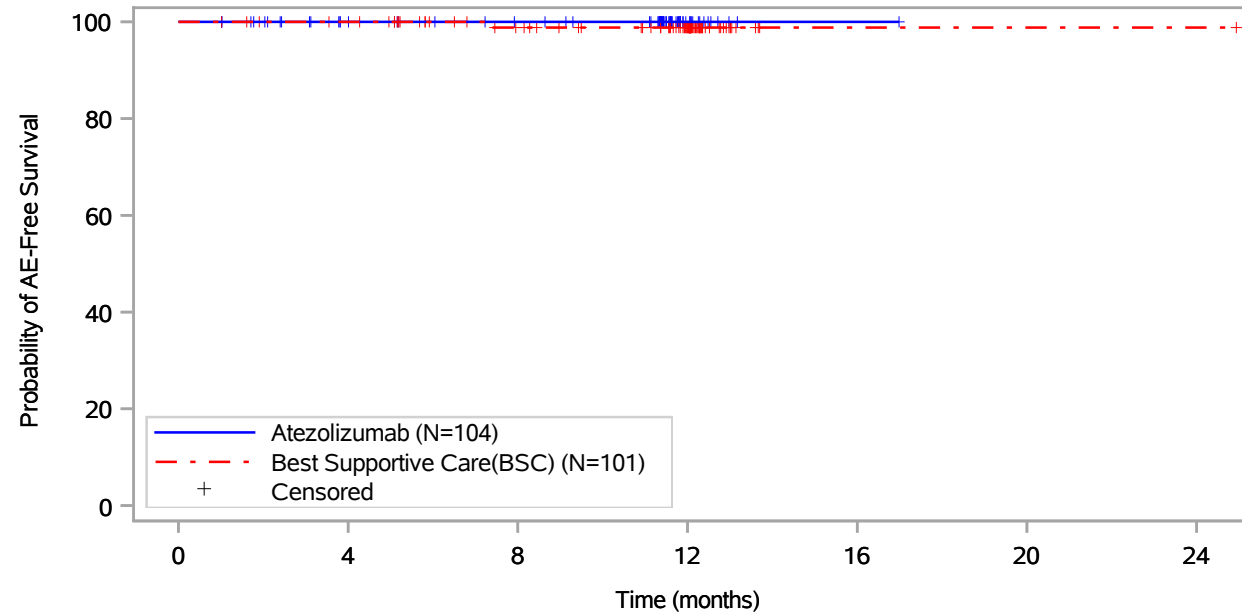
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

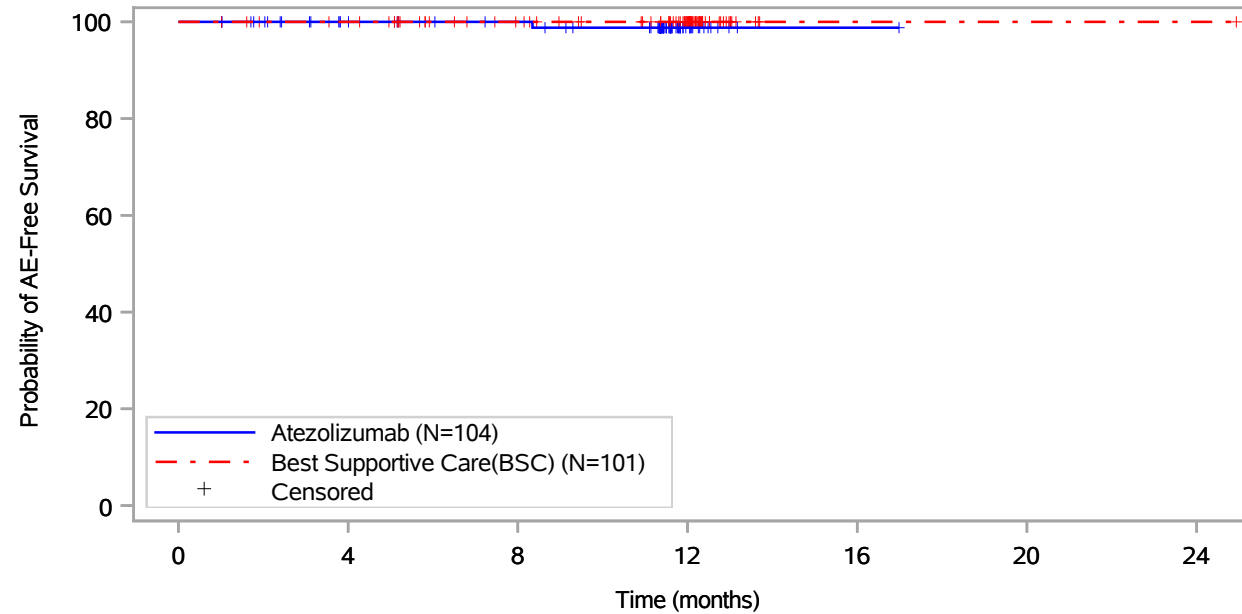
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebral arteriosclerosis



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

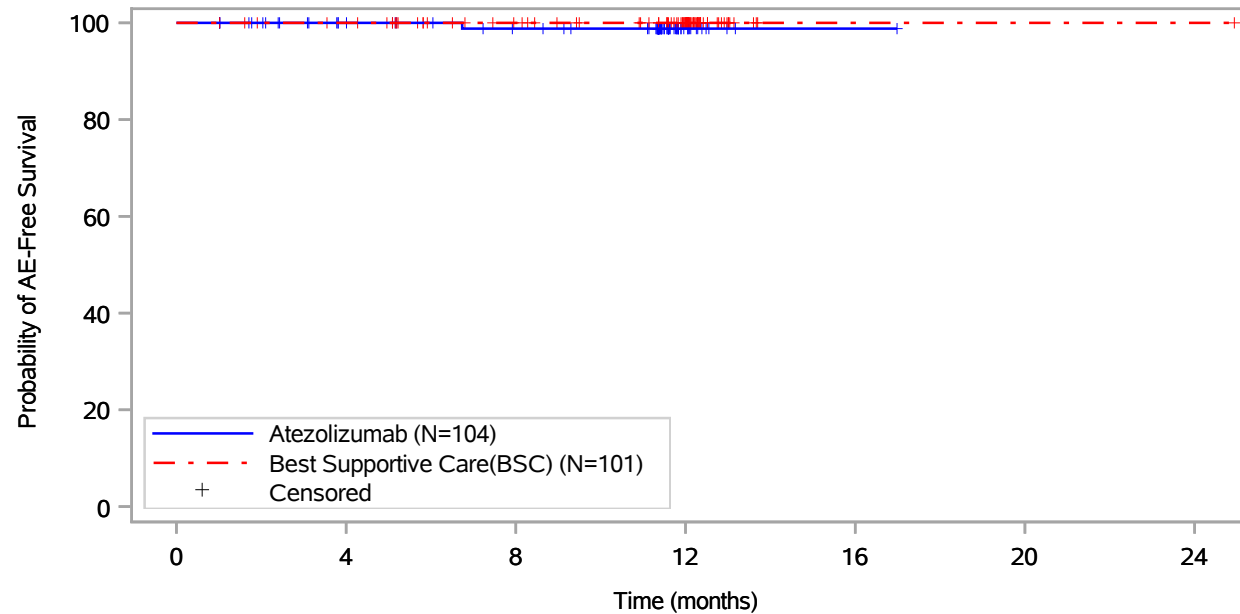
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebral infarction



Patients at risk							
Atezolizumab (N=104)	104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

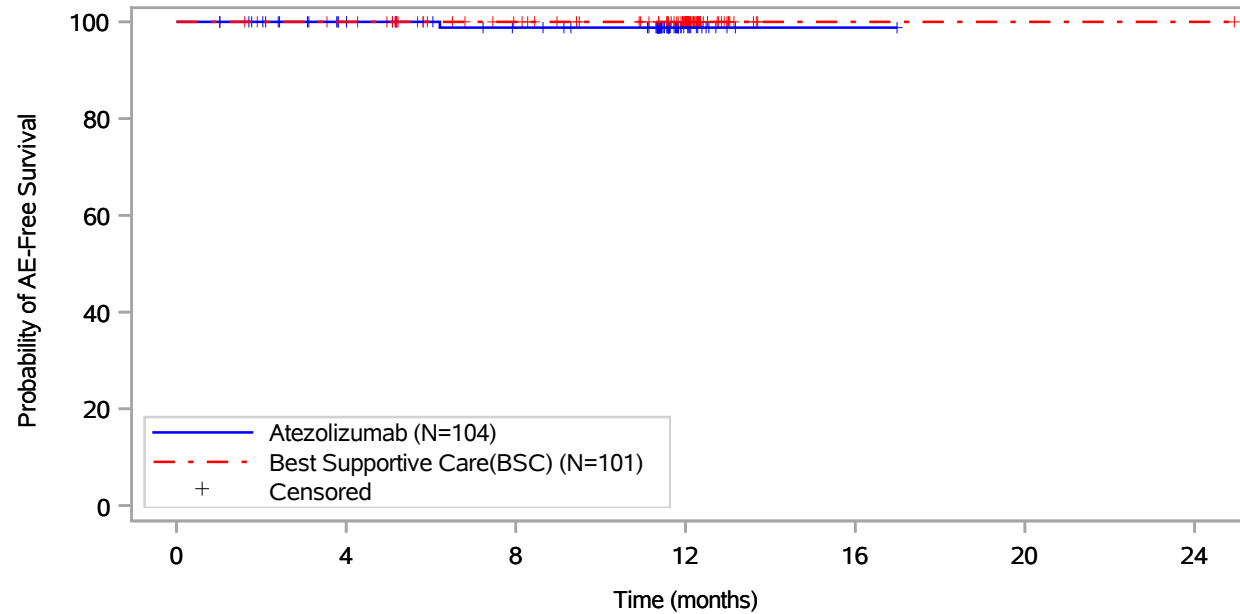
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Cognitive disorder



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

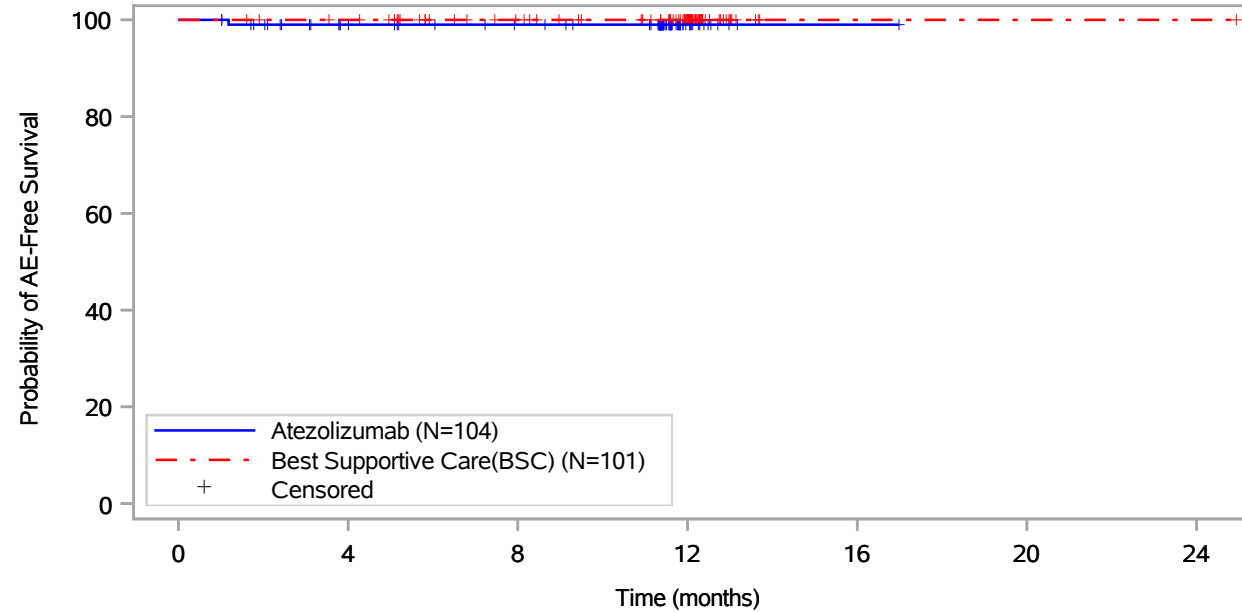
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

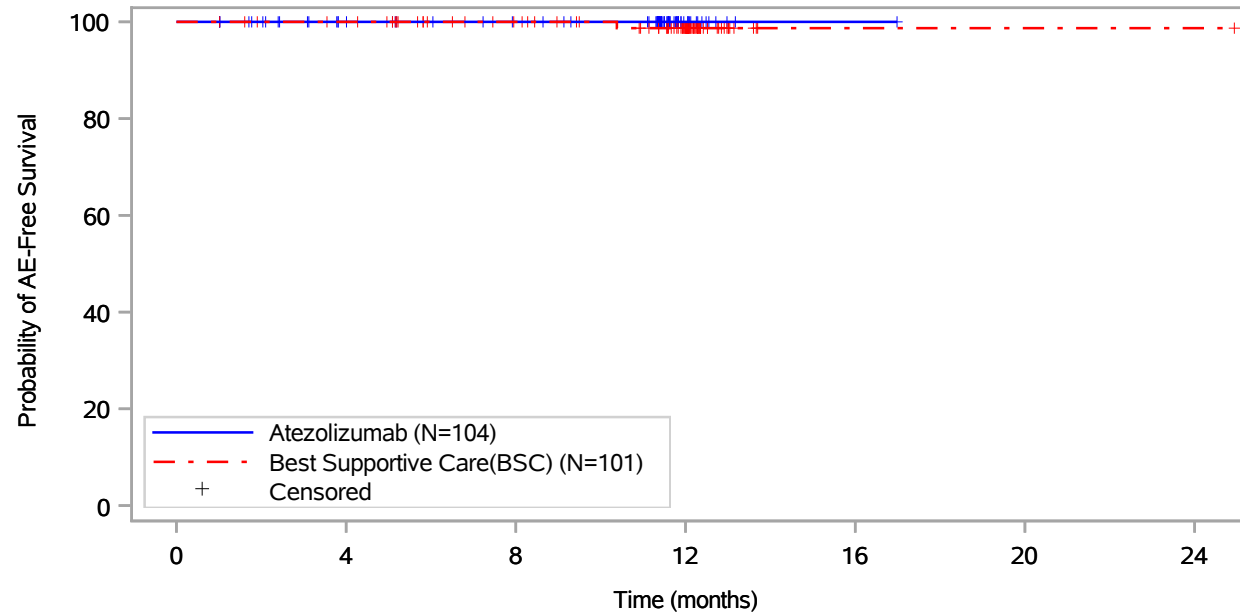
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Disturbance in attention



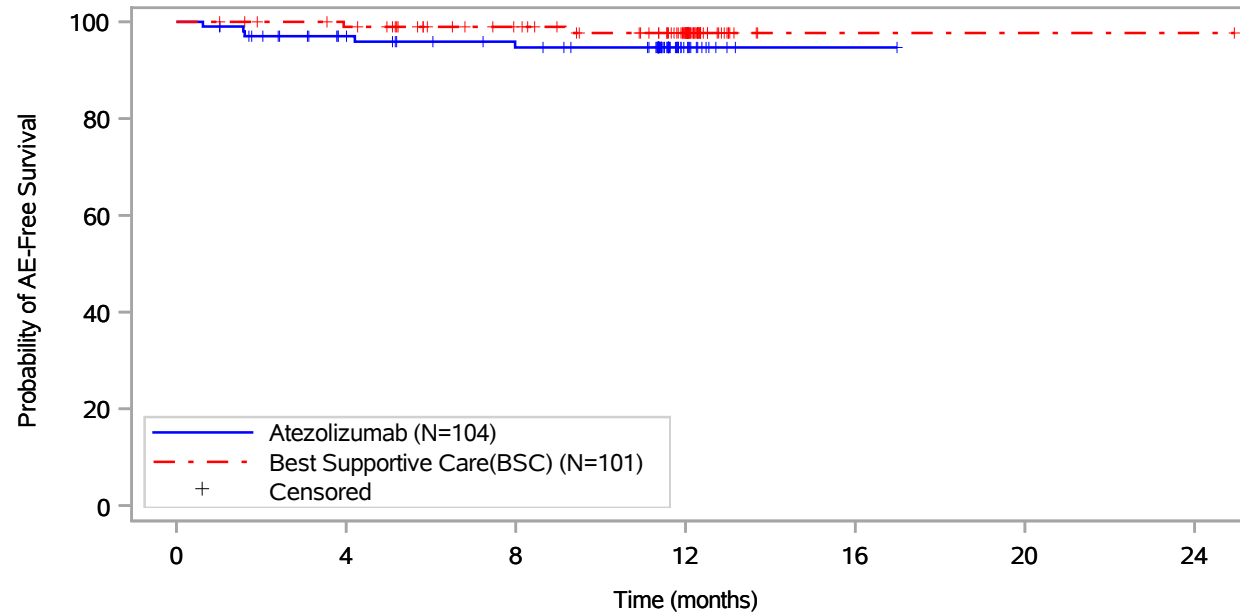
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Dizziness



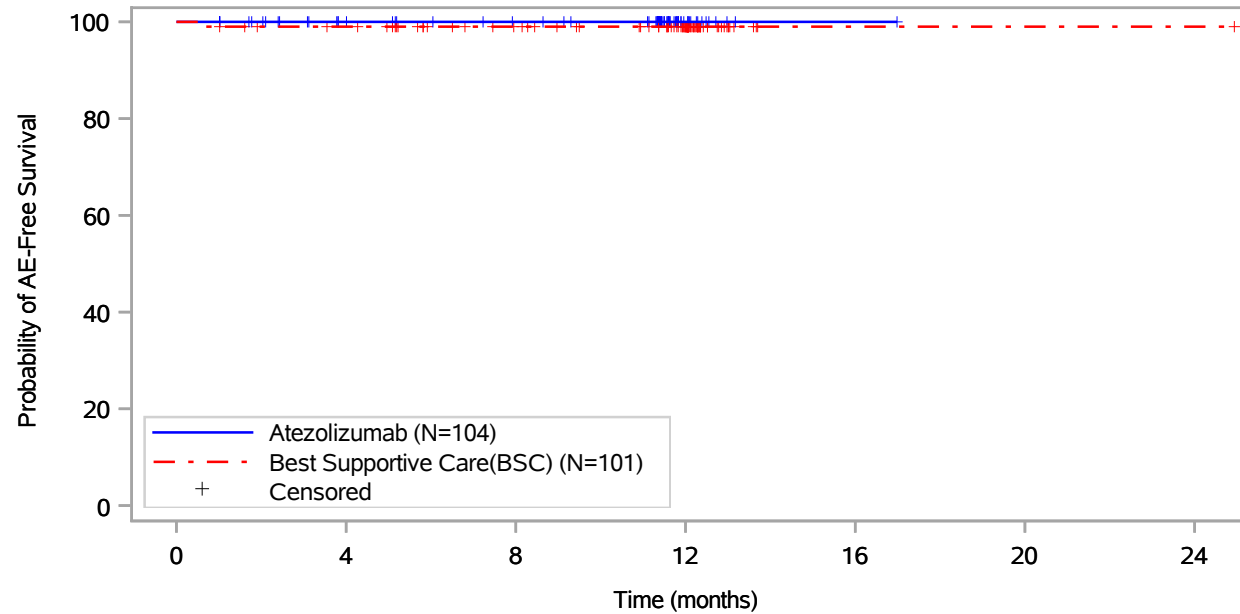
Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	85	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Dysaesthesia



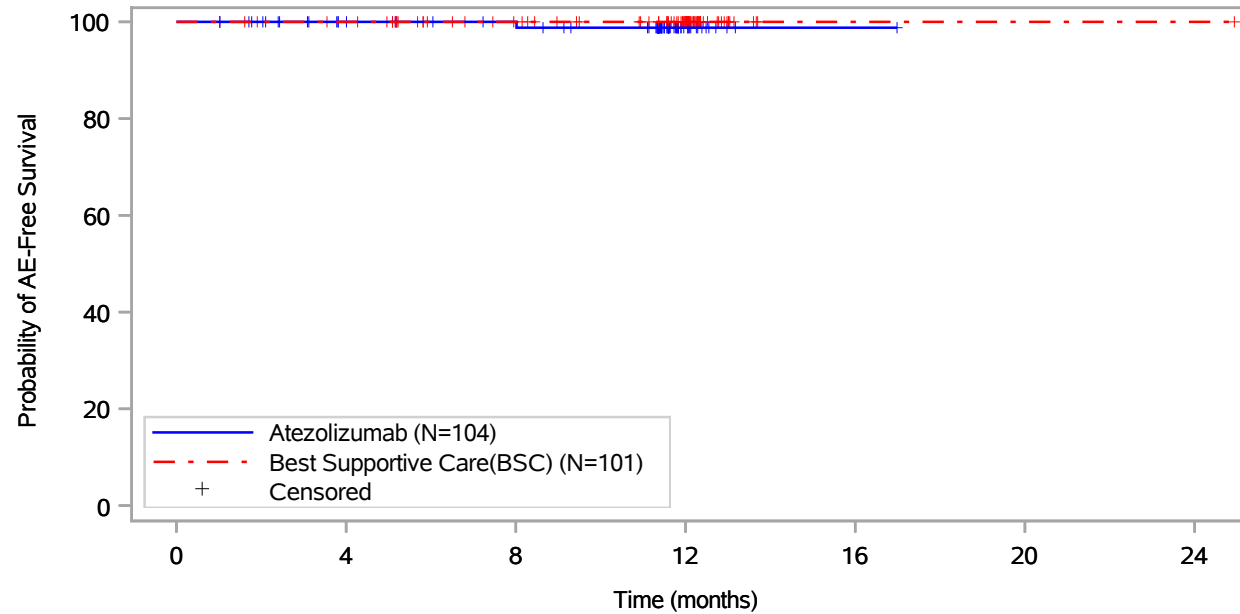
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Encephalopathy



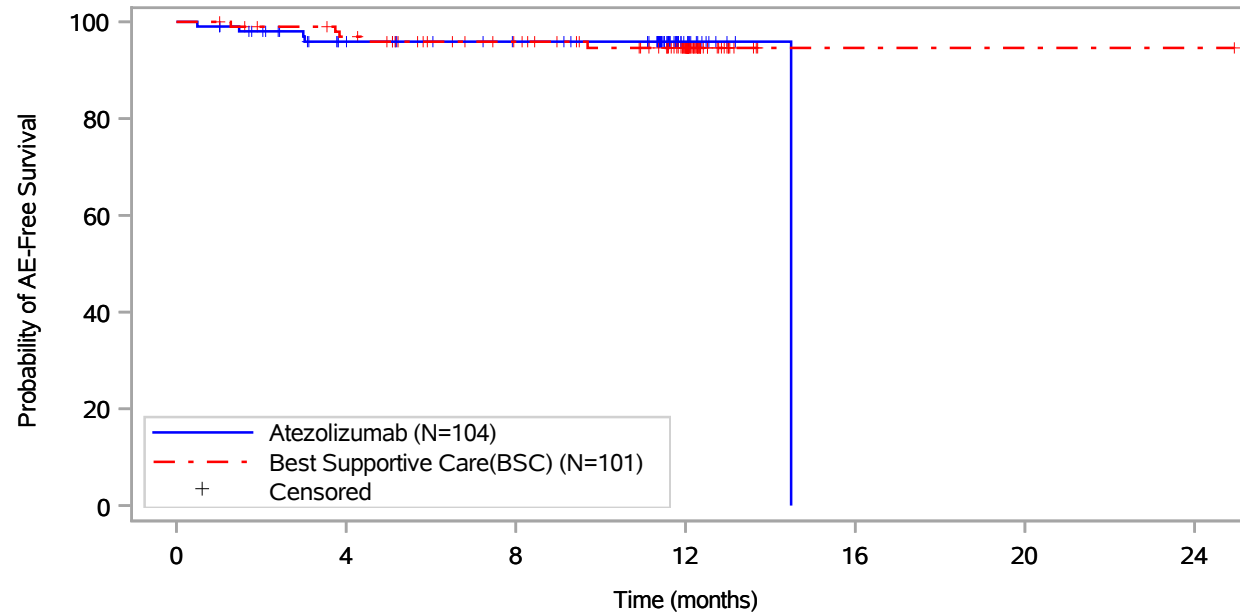
Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Headache



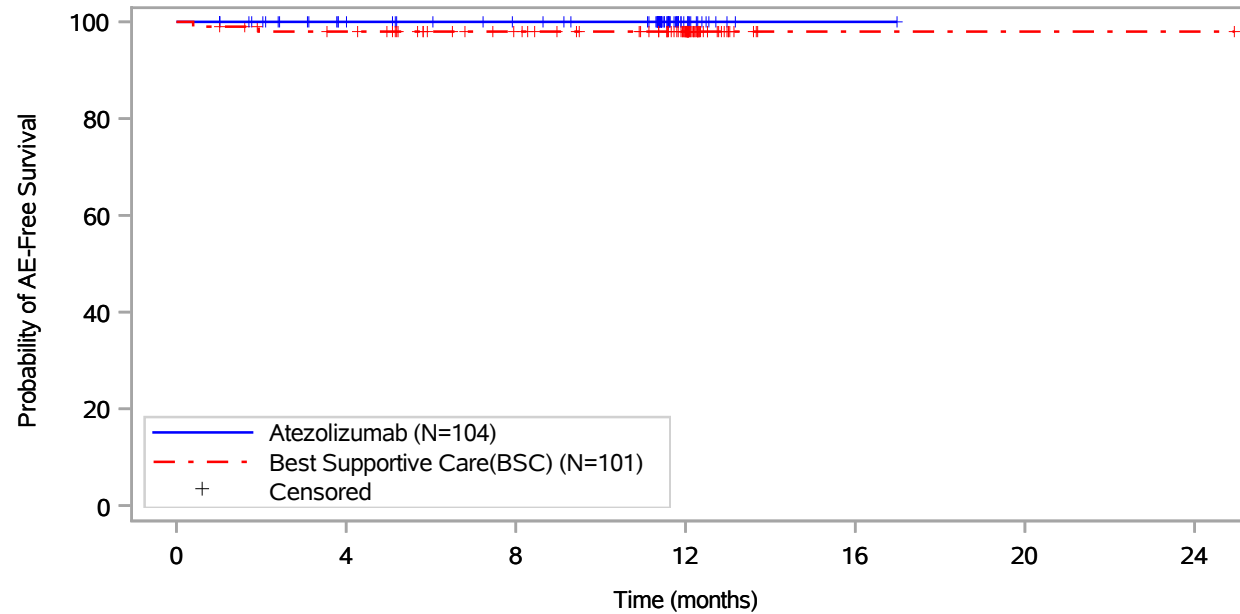
Patients at risk							
Atezolizumab (N=104)	104	85	78	14	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	86	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	16	43	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Hypoaesthesia



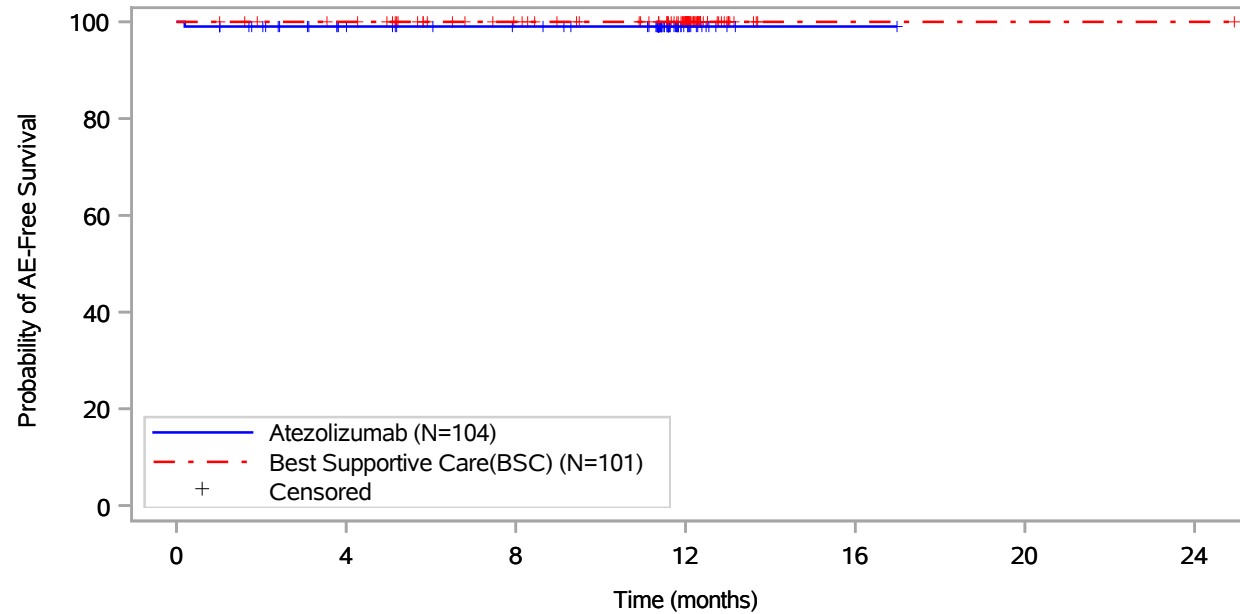
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Lethargy



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

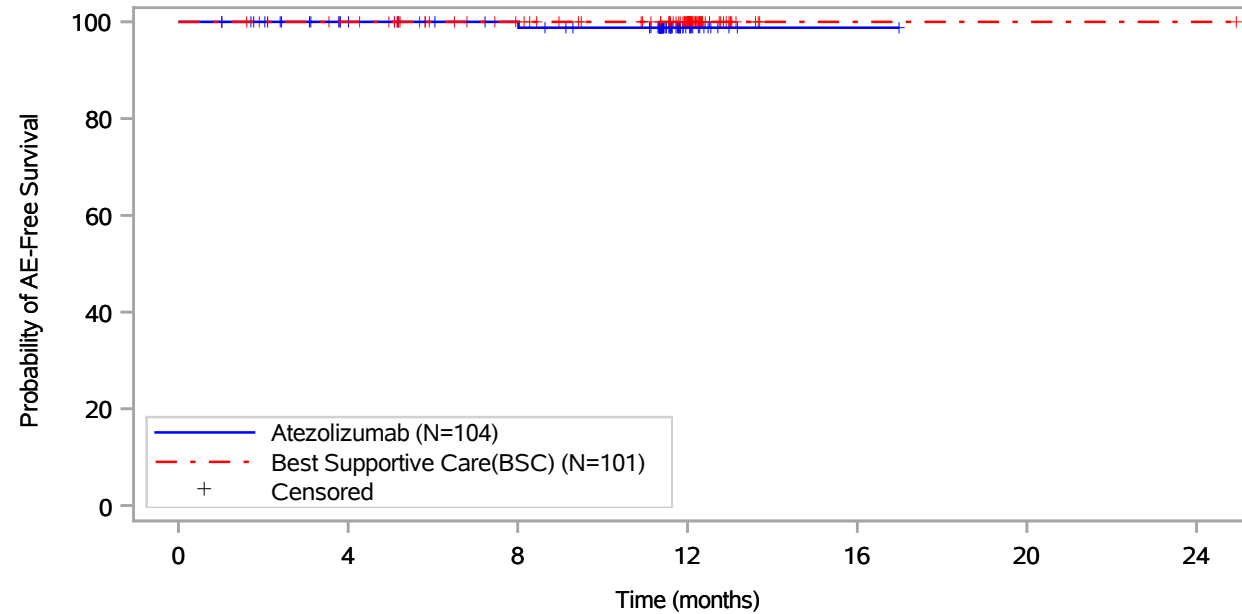
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Loss of consciousness



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

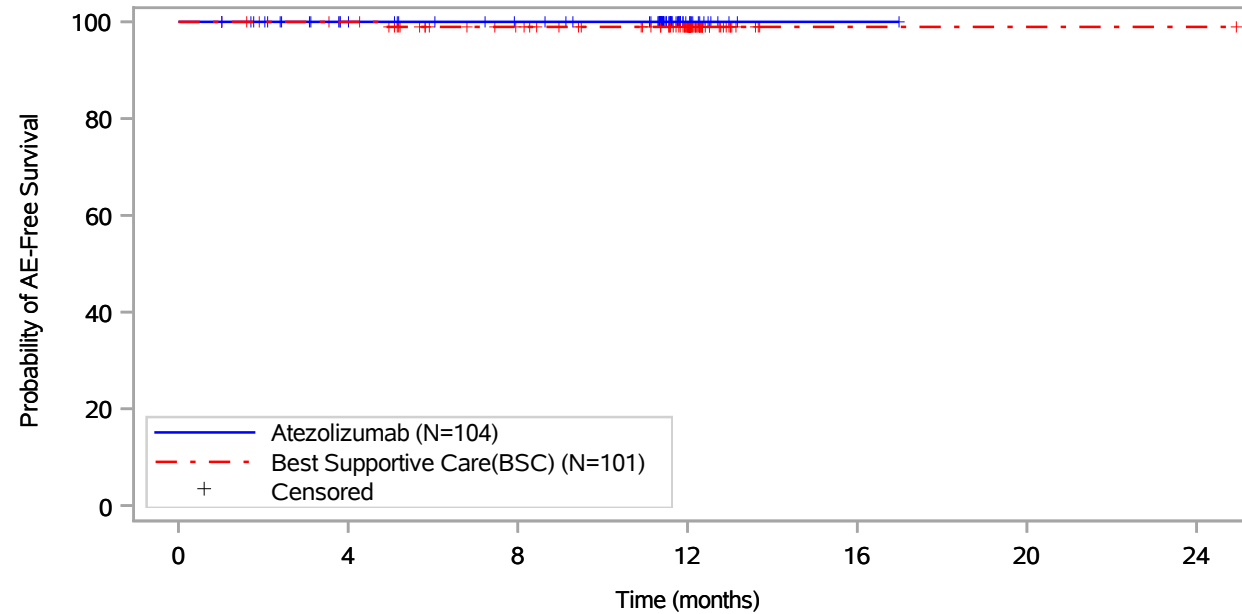
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Memory impairment



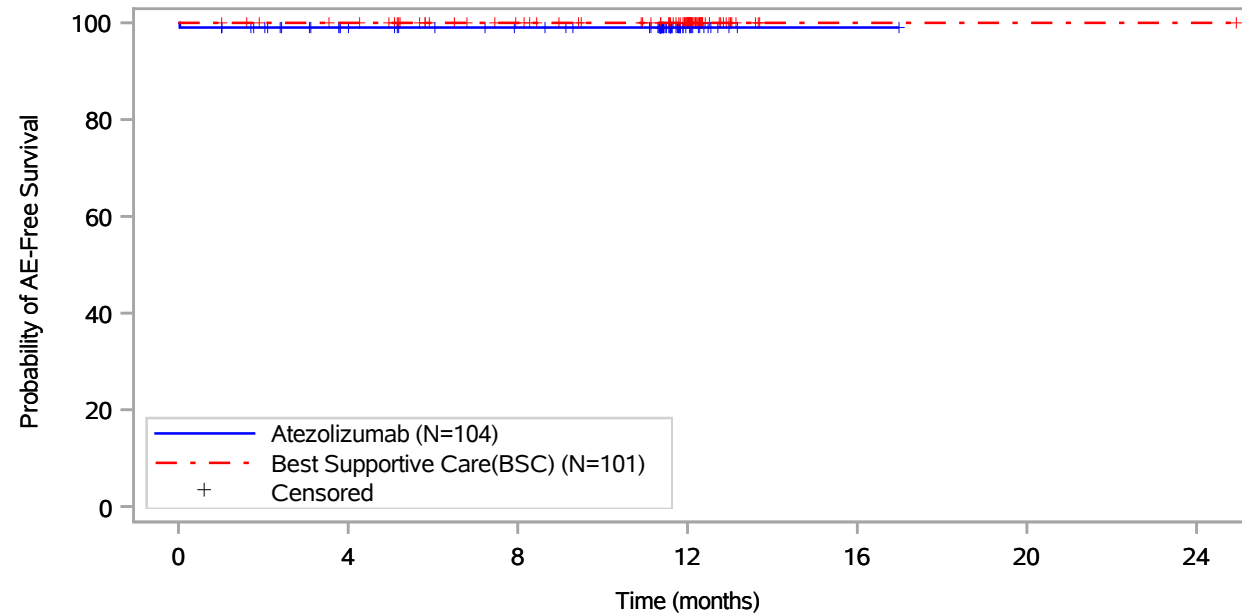
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Migraine



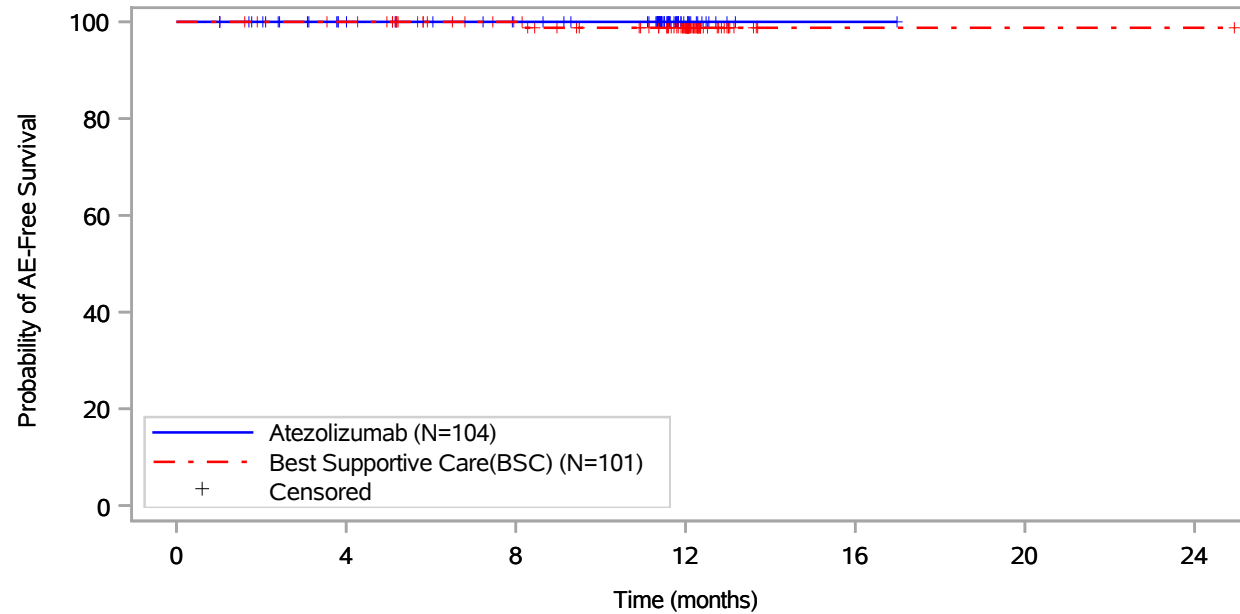
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Myelopathy



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

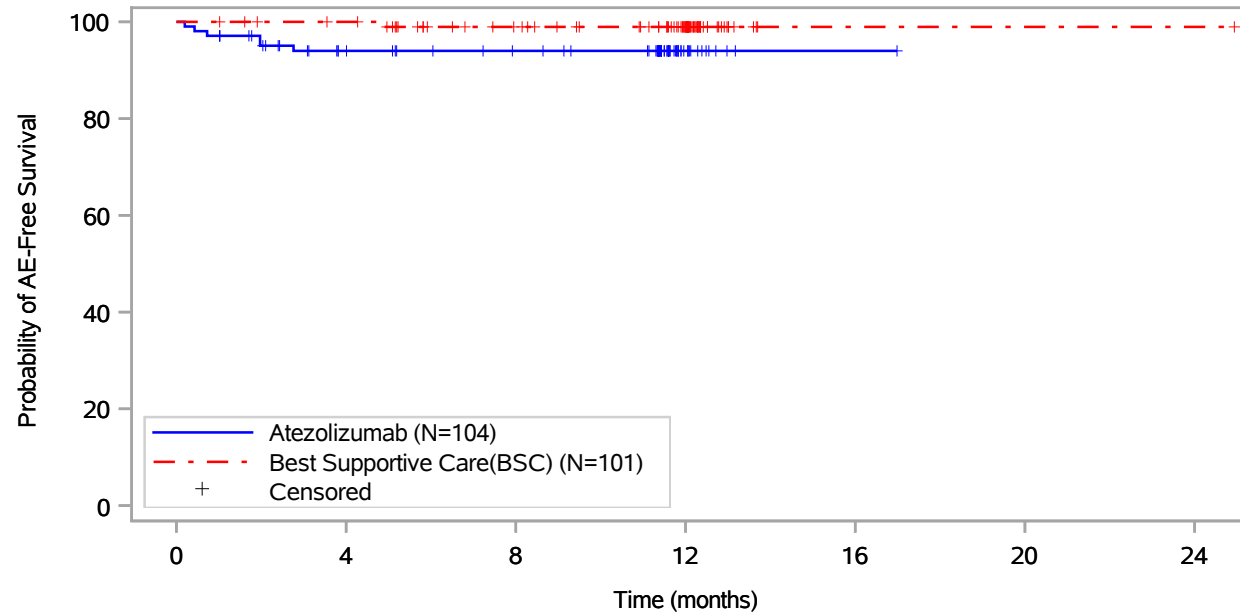
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Neuropathy peripheral



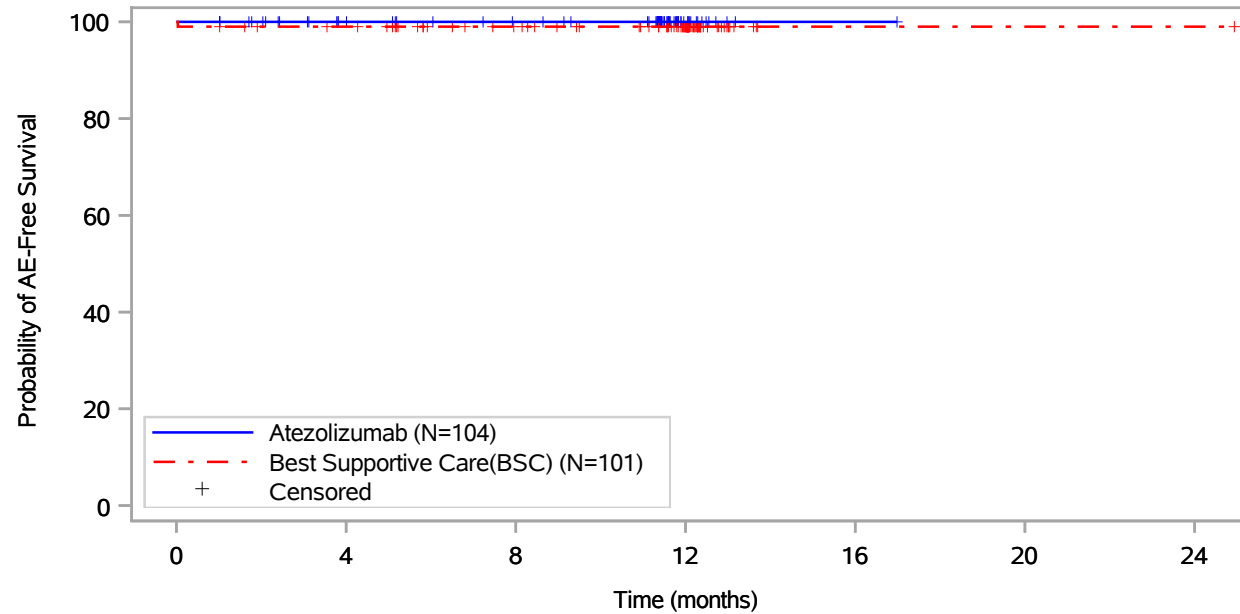
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	83	76	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	85	97	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Neurotoxicity



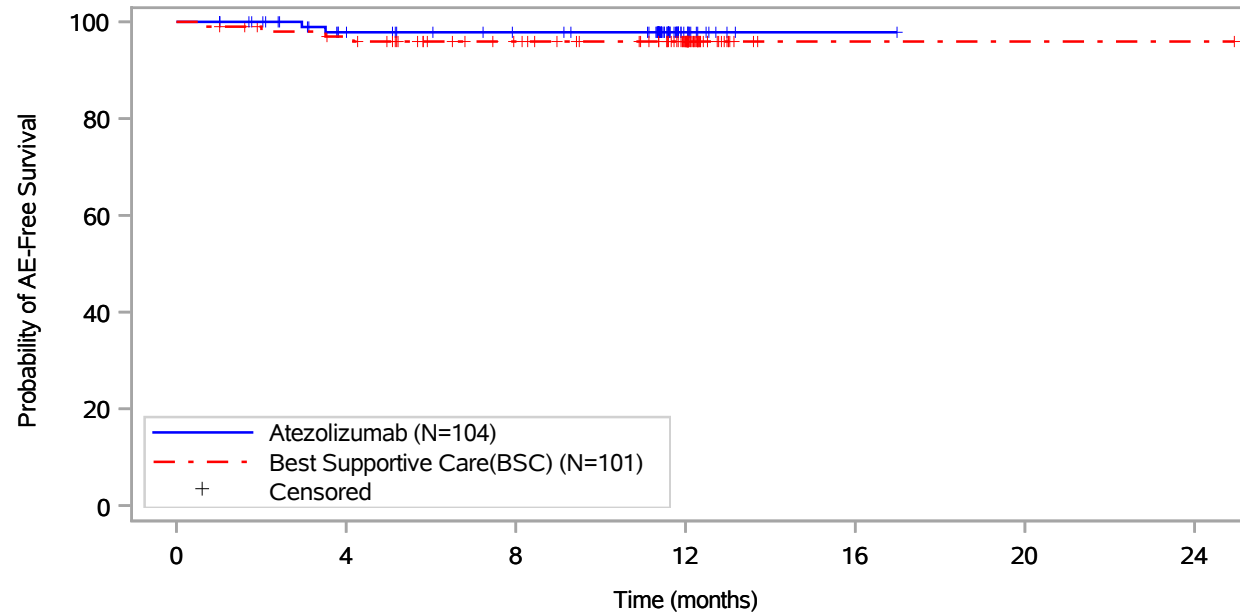
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Paraesthesia



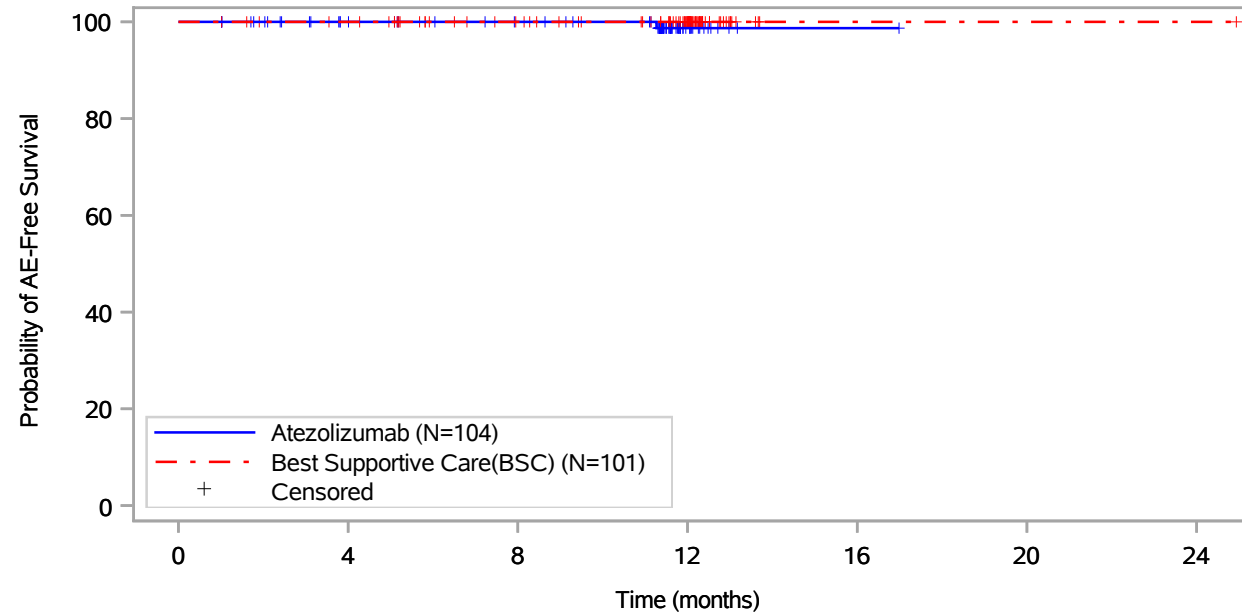
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	80	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	79	51	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	96	96	96	96

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Parosmia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

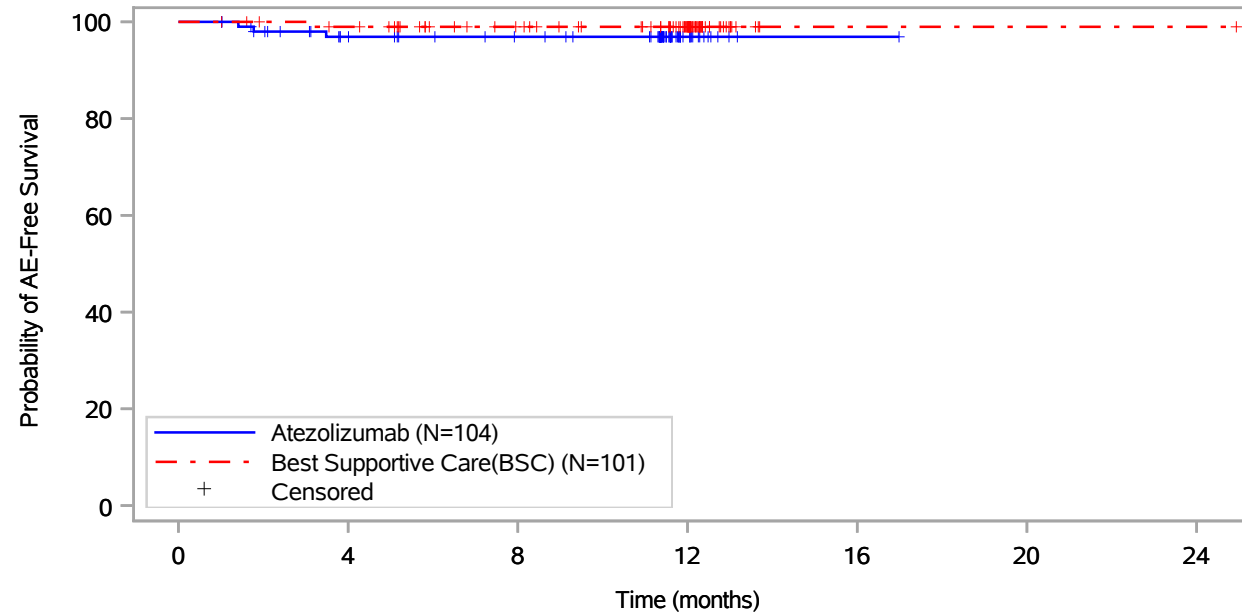
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



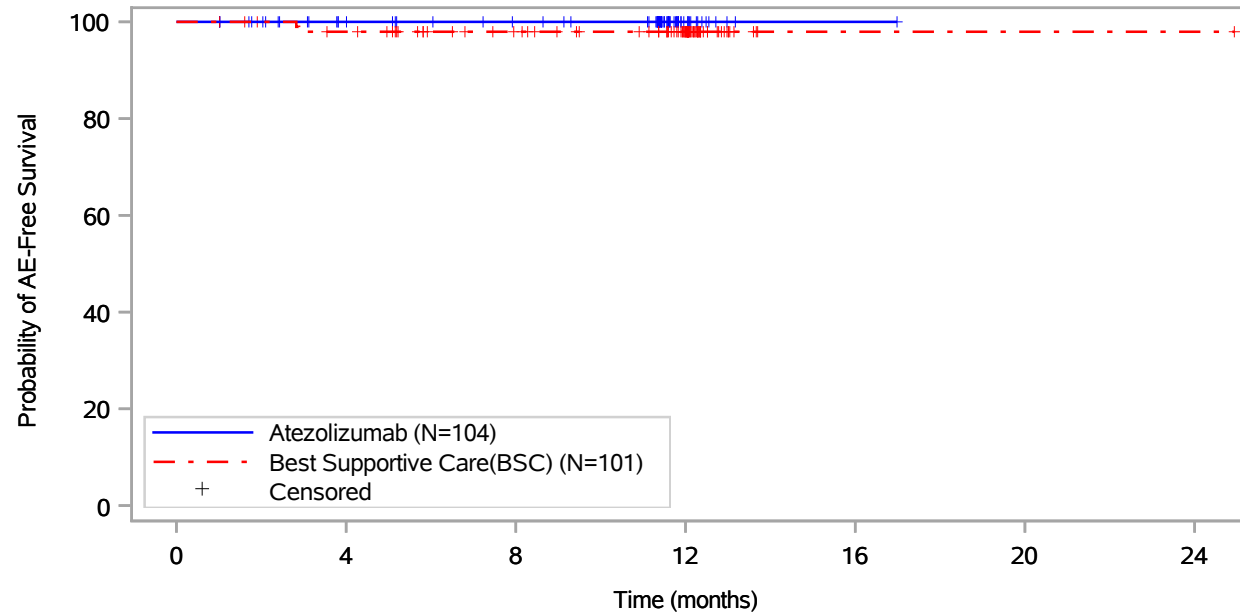
Patients at risk							
Atezolizumab (N=104)	104	87	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Polyneuropathy



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98

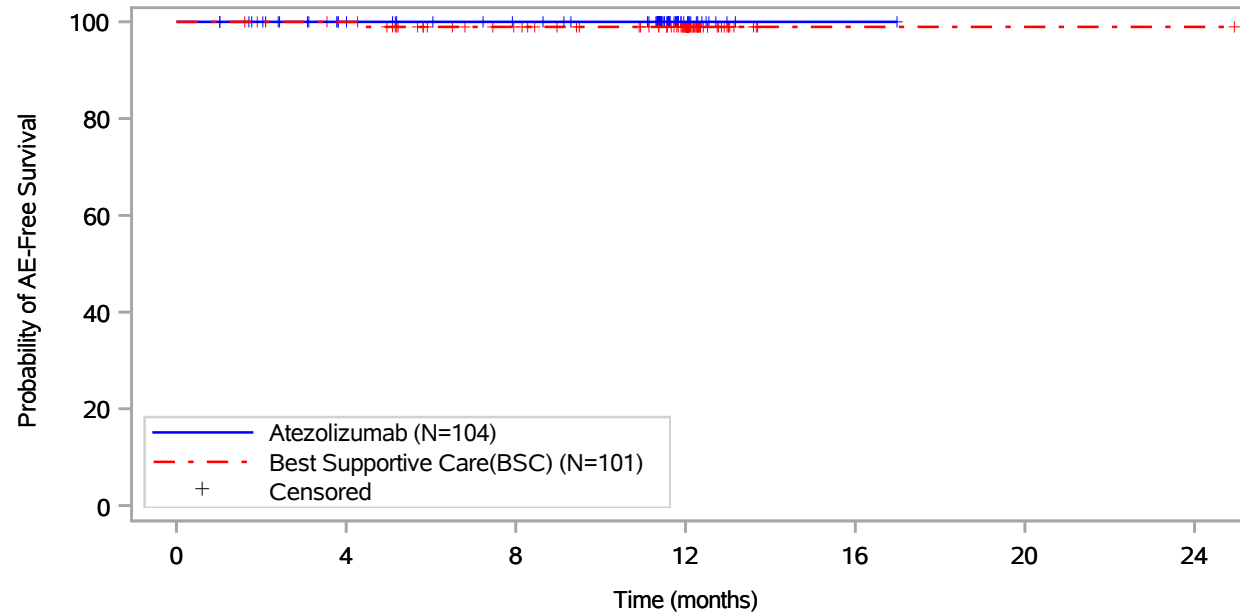
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



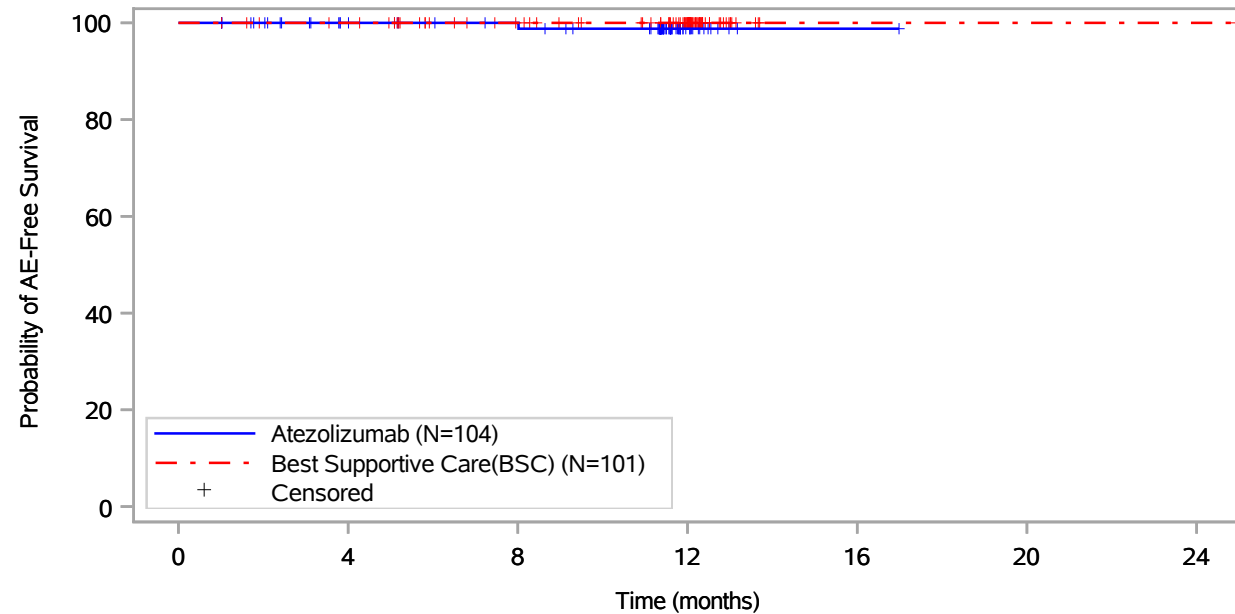
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Seizure



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

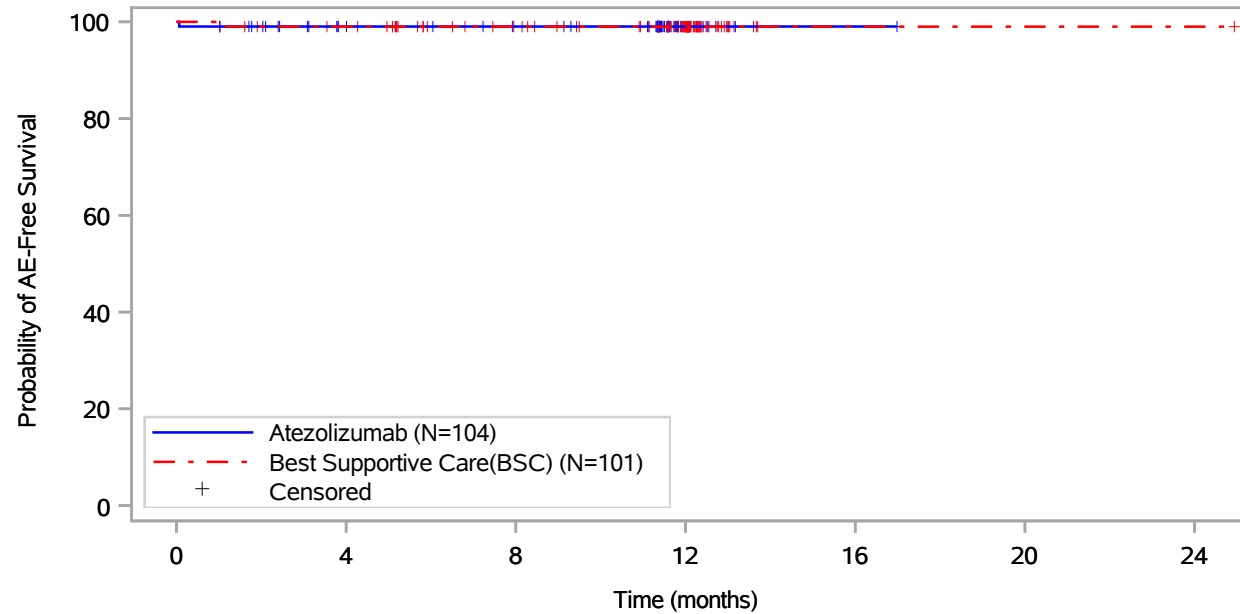
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Somnolence



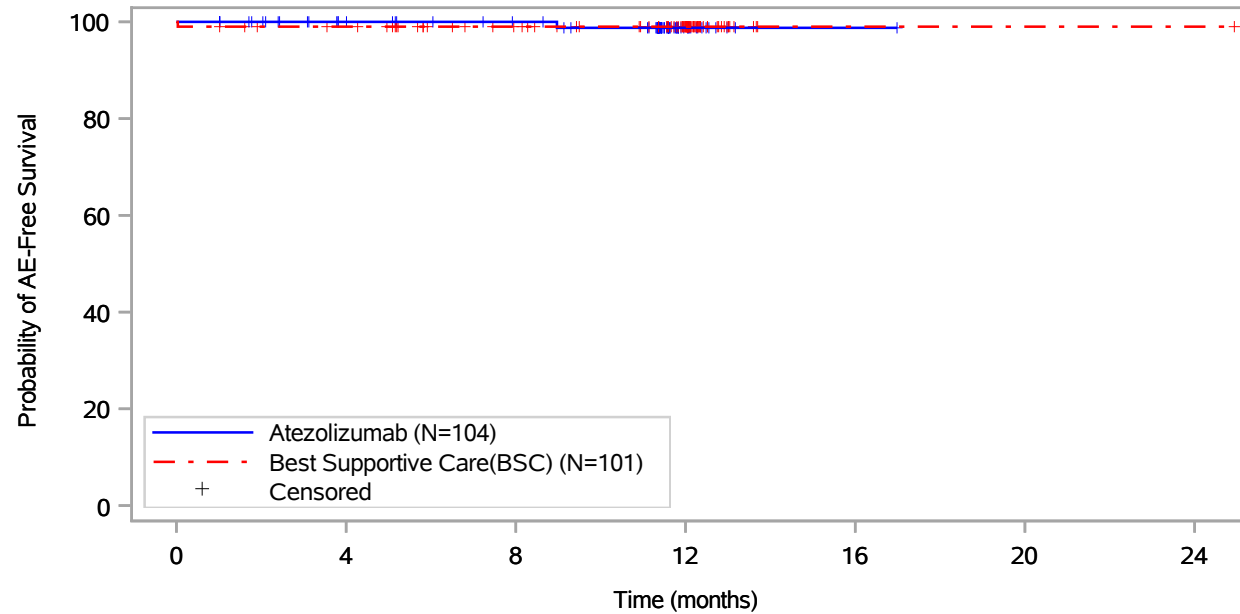
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Nervous system disorders, Syncope



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

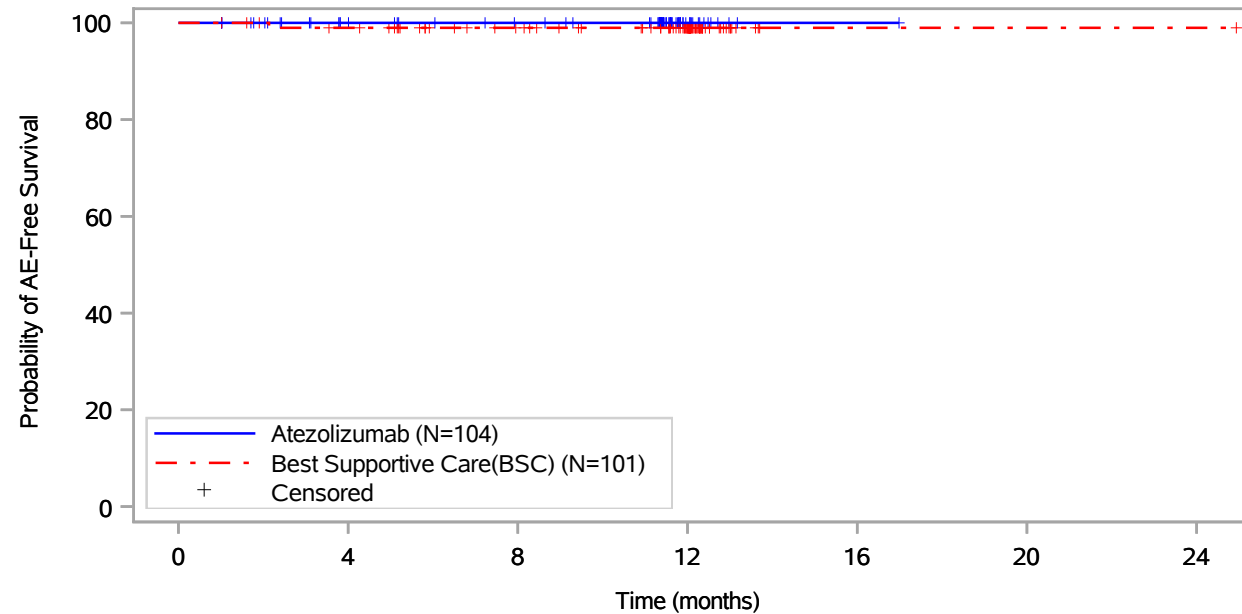
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Tension headache



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

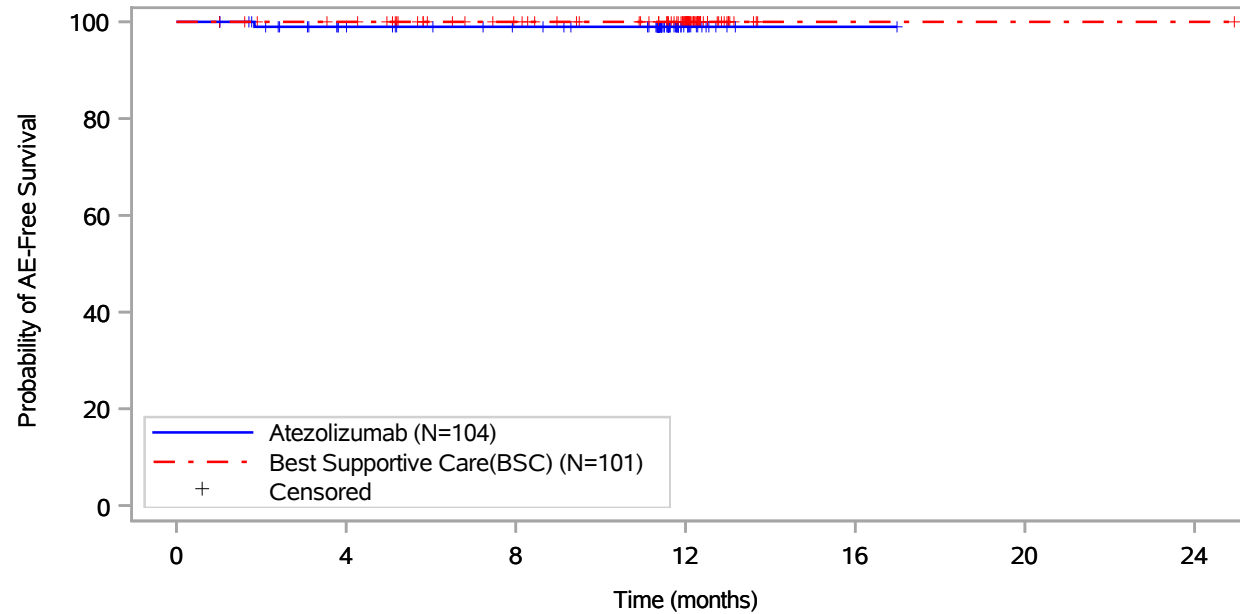
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Transient ischaemic attack



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

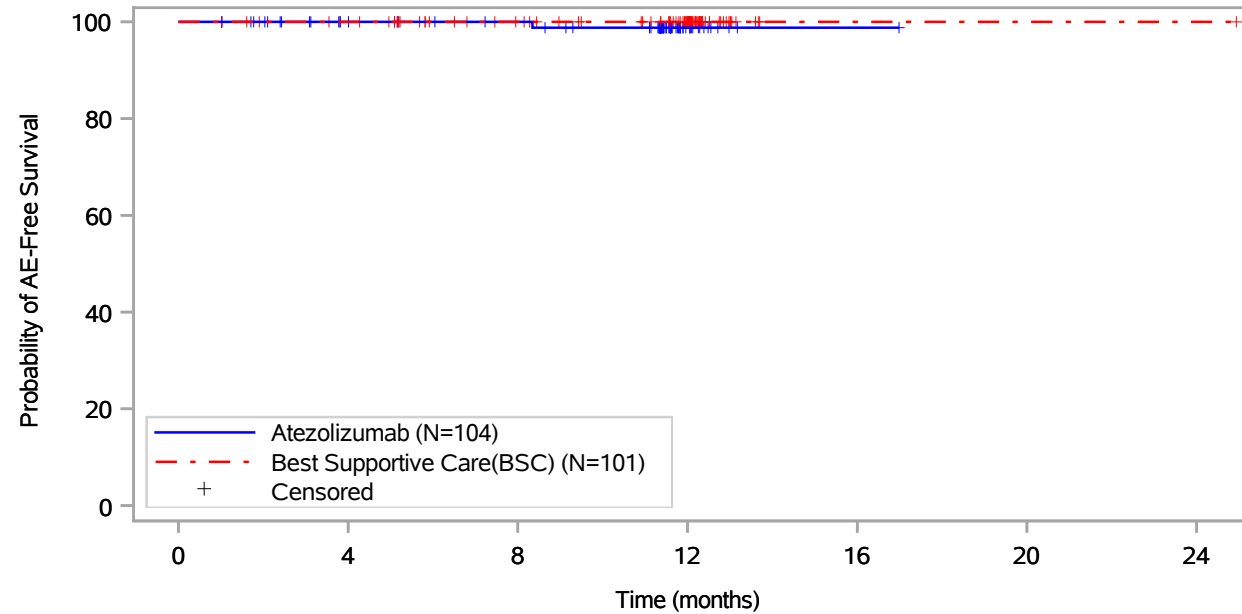
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Upper motor neurone lesion



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

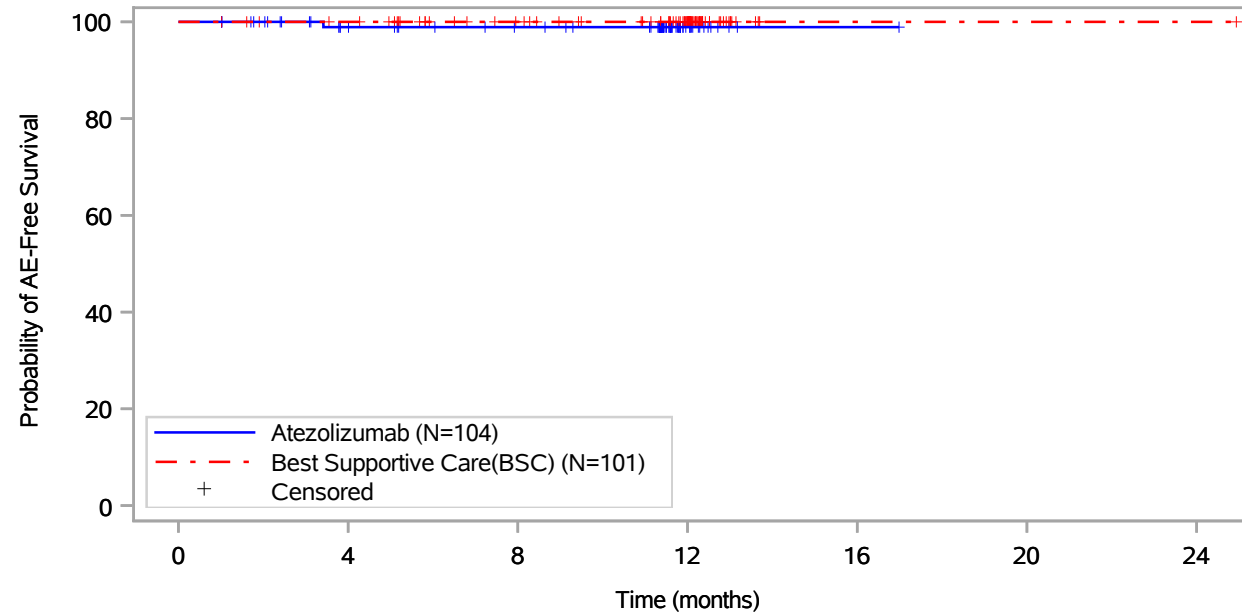
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Nervous system disorders, Vocal cord paralysis



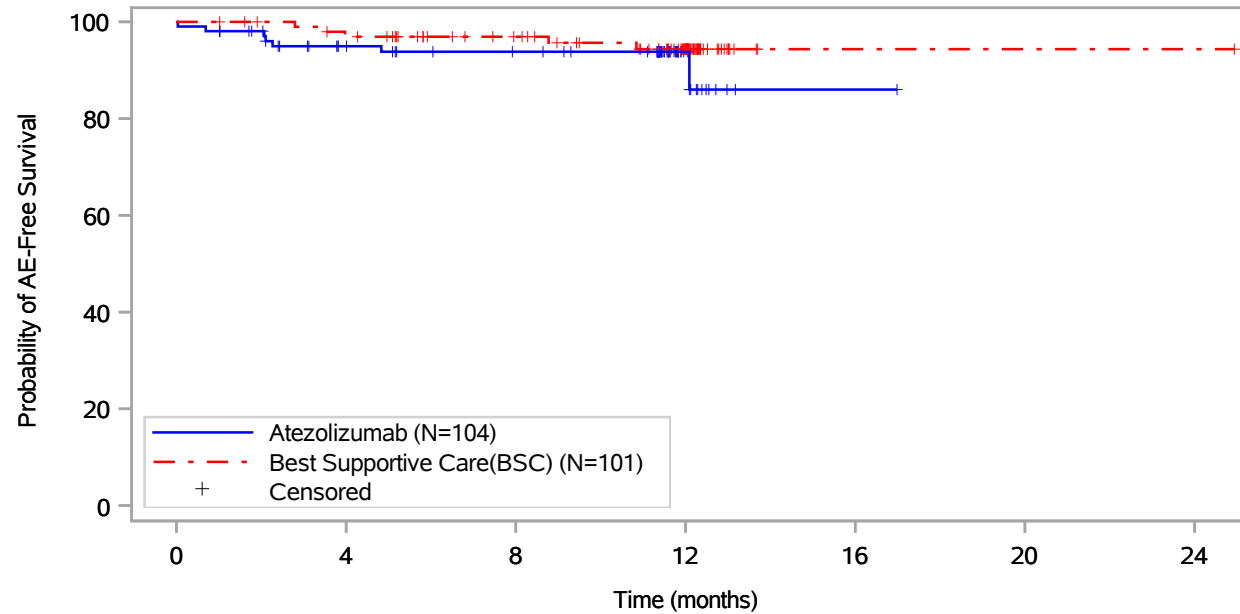
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, All



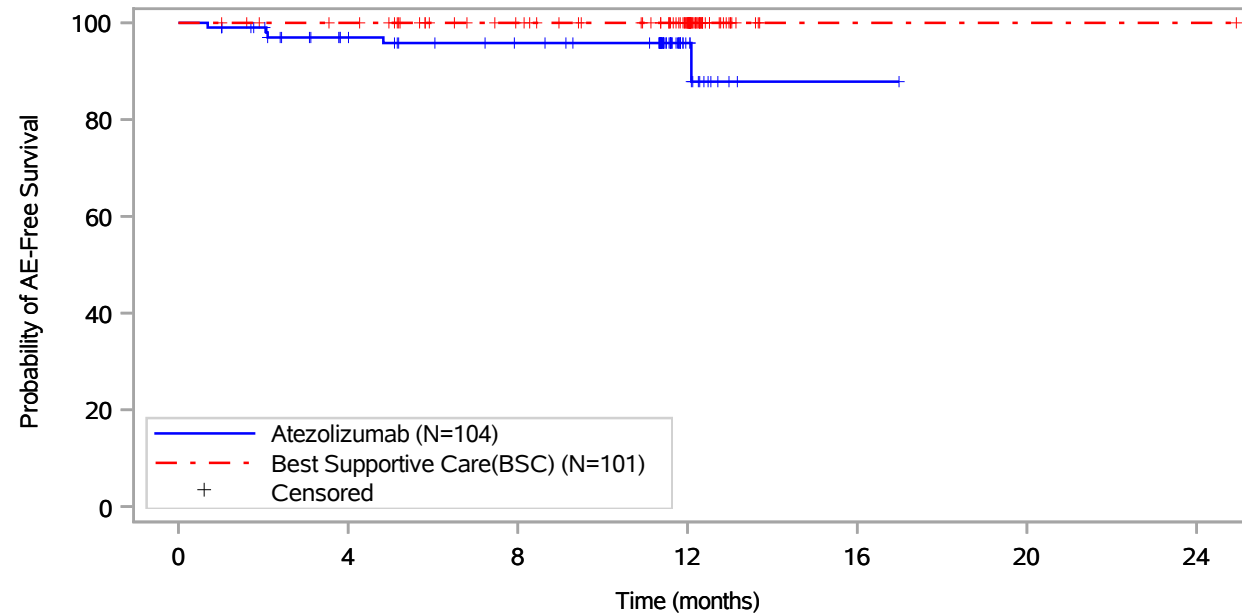
Patients at risk							
Atezolizumab (N=104)	104	84	77	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	80	51	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	84	96	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, Anxiety



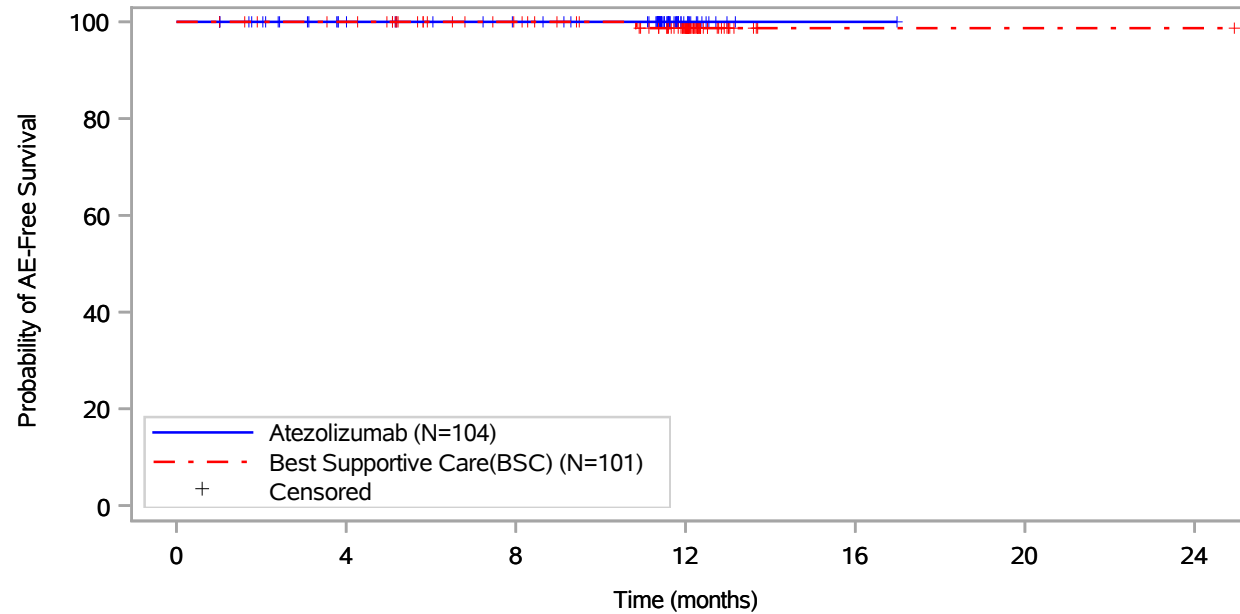
Patients at risk							
Atezolizumab (N=104)	104	86	78	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	86	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, Depressed mood



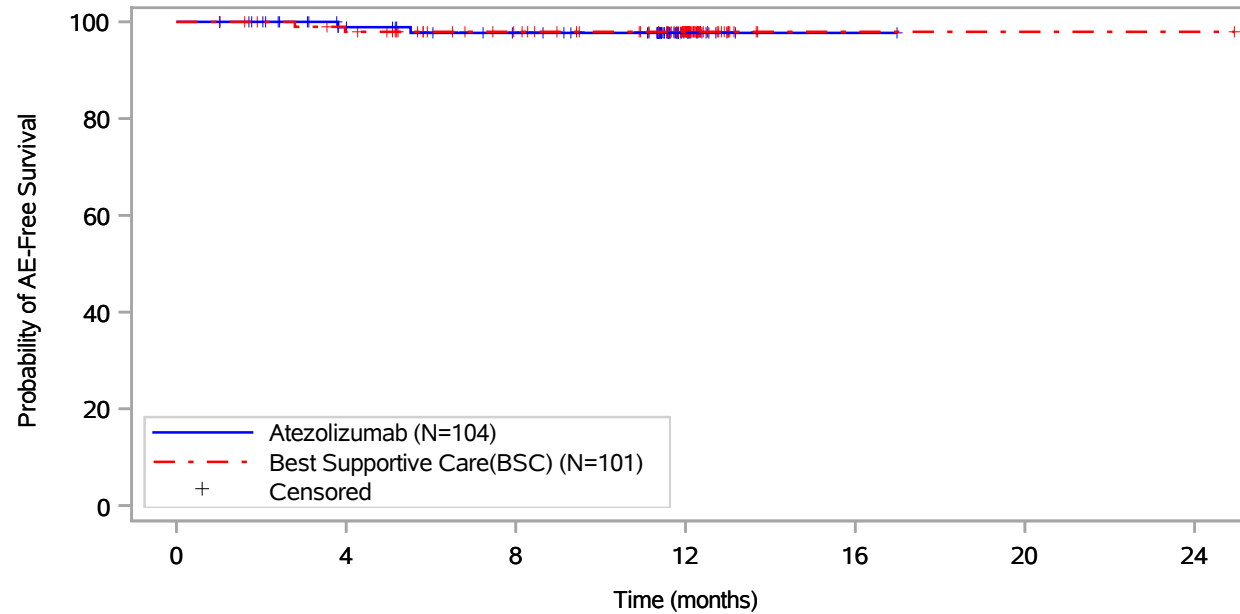
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, Depression



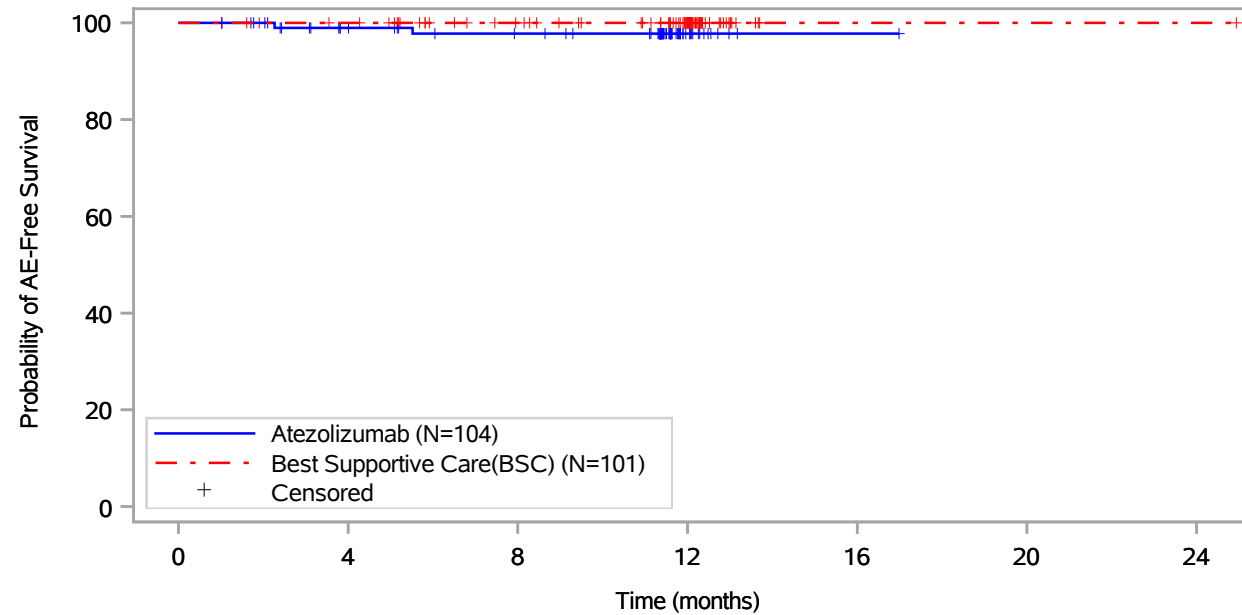
Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, Insomnia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

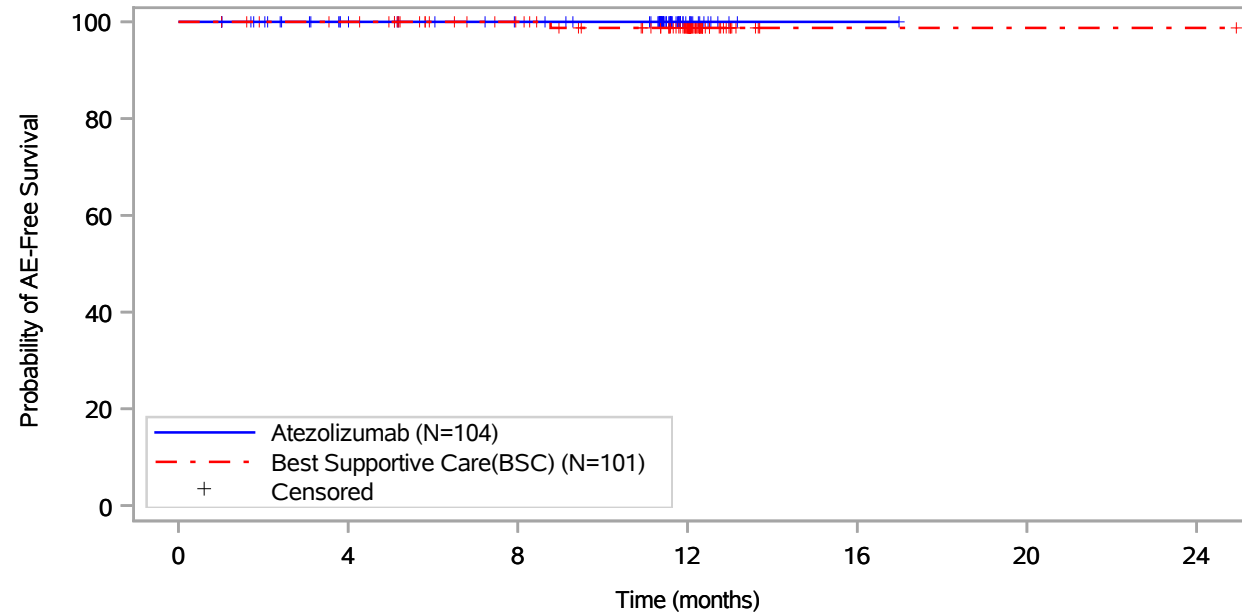
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Psychiatric disorders, Mental status changes



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

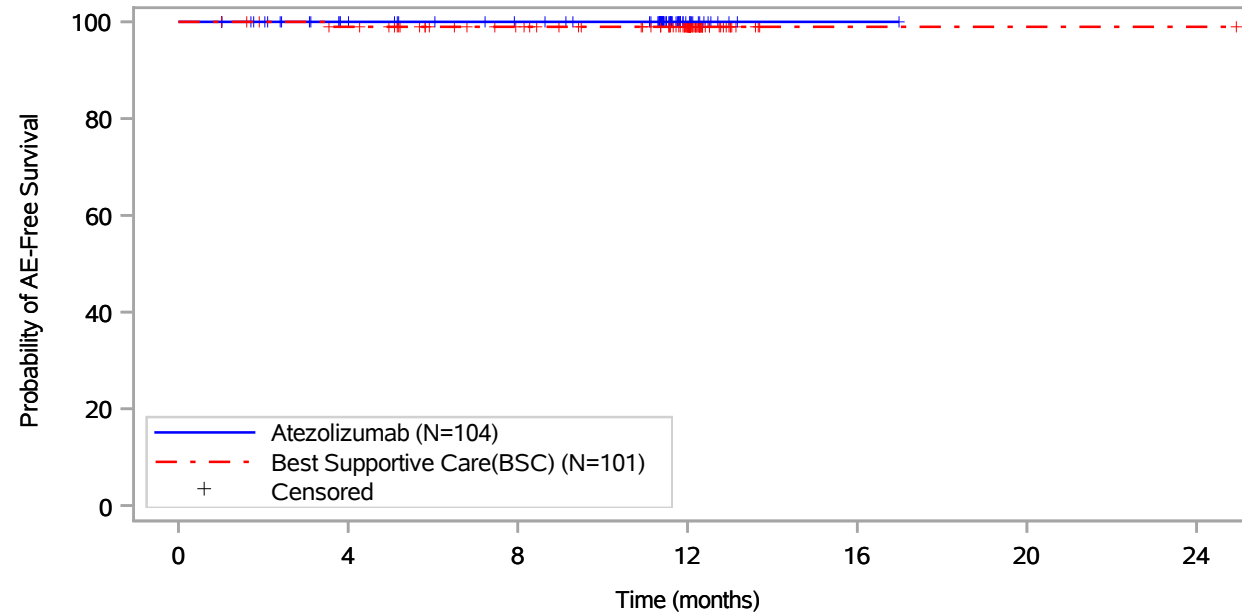
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Psychiatric disorders, Psychiatric symptom



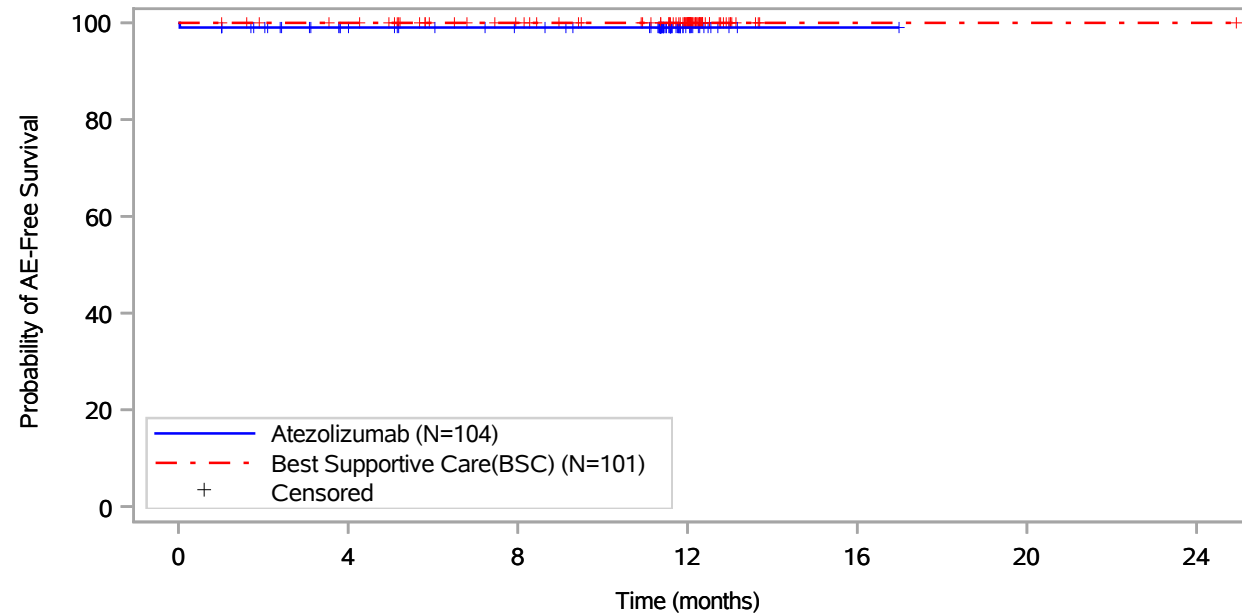
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Psychiatric disorders, Sleep disorder



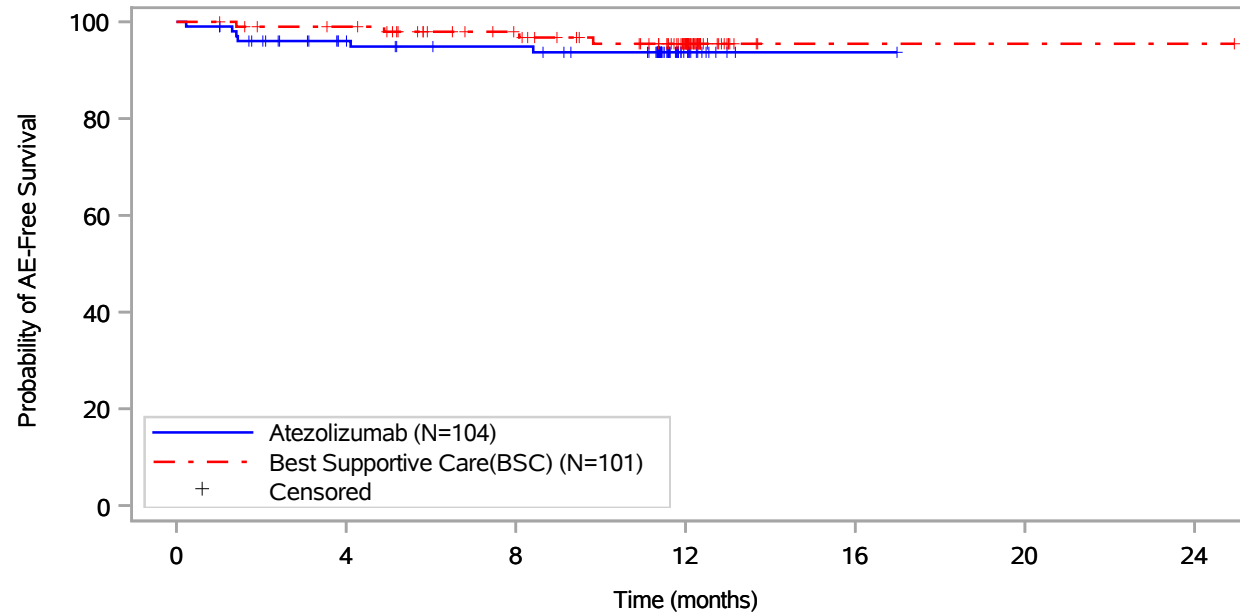
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Renal and urinary disorders, All



Patients at risk							
Atezolizumab (N=104)	104	85	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	19	84	97	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	96	96	96

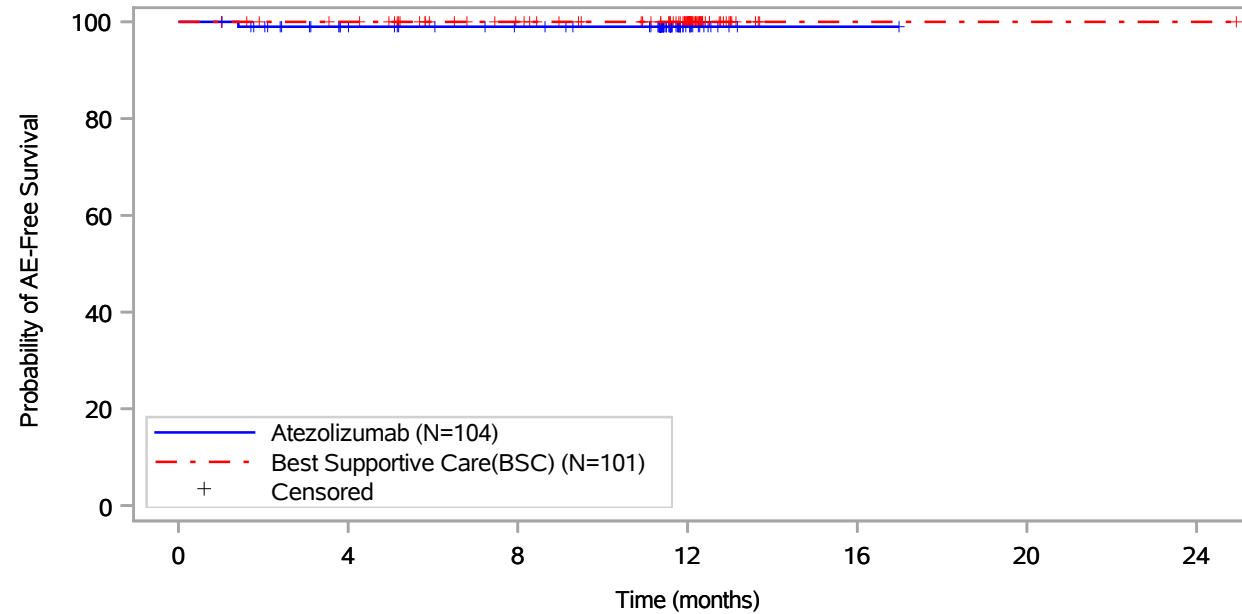
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Acute kidney injury



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

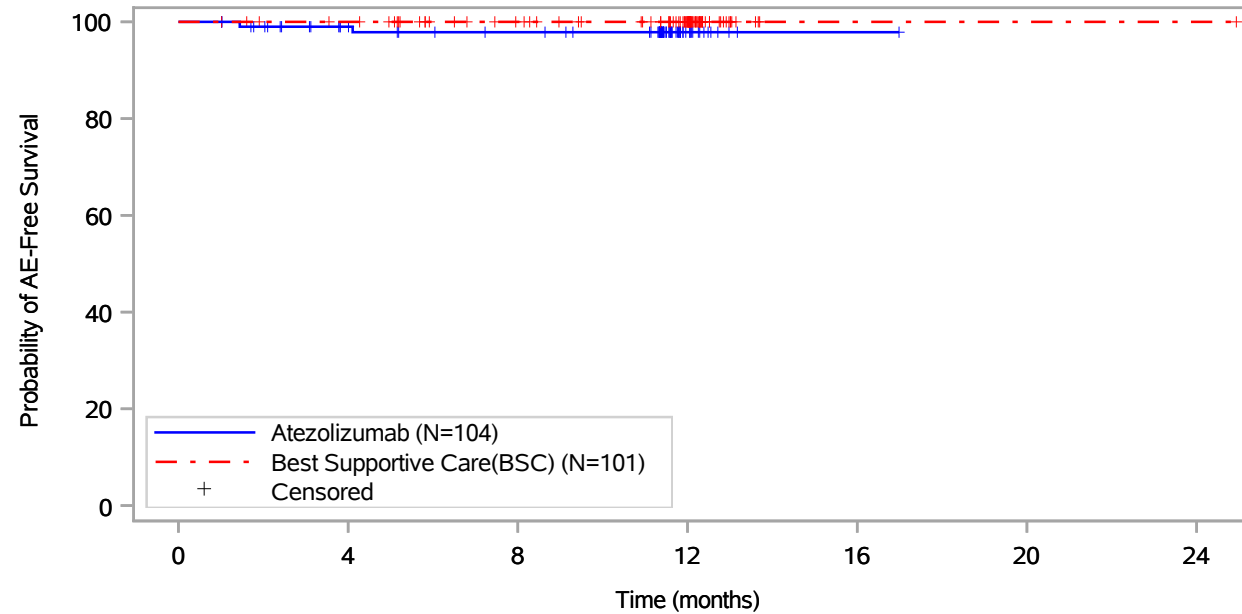
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



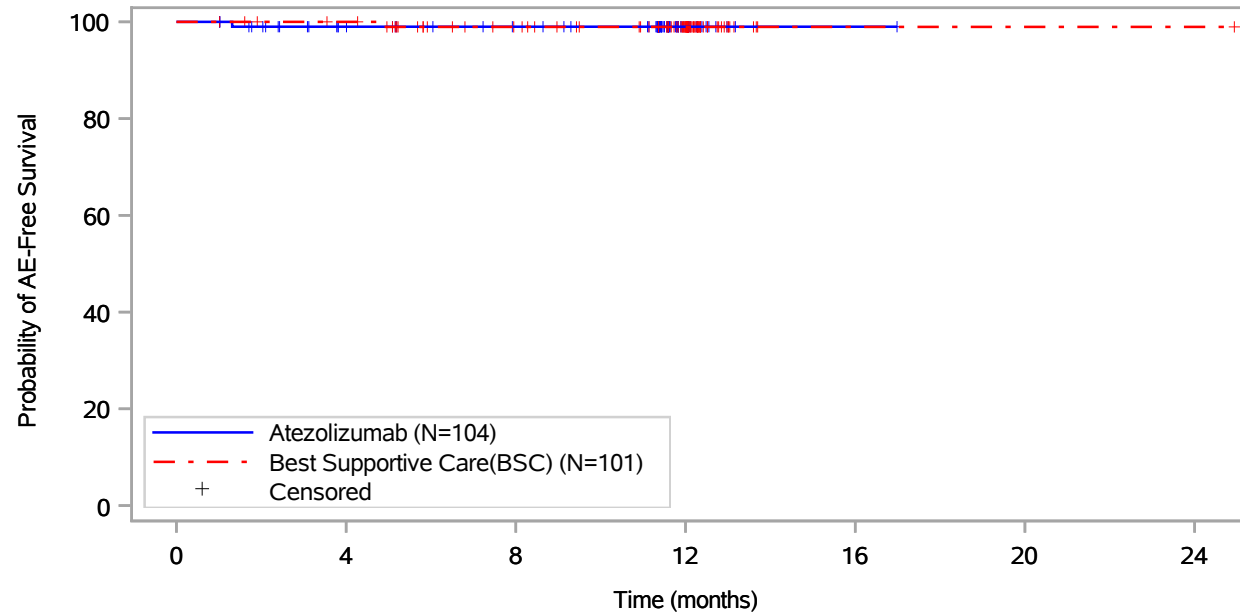
Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Renal and urinary disorders, Dysuria



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

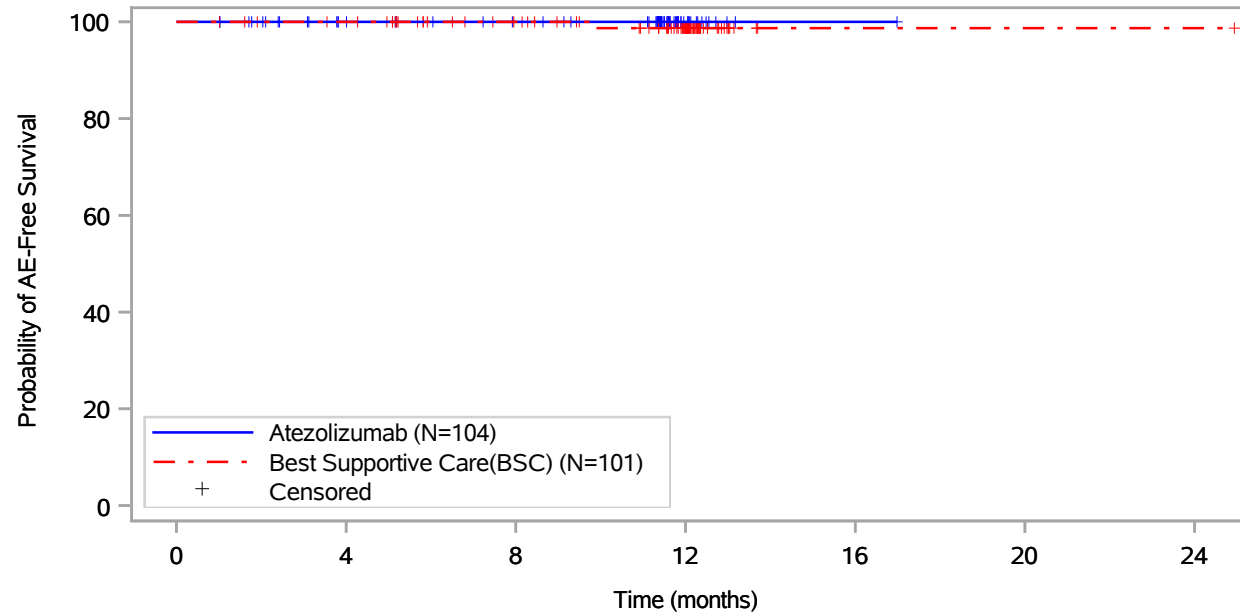
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Lower urinary tract symptoms



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

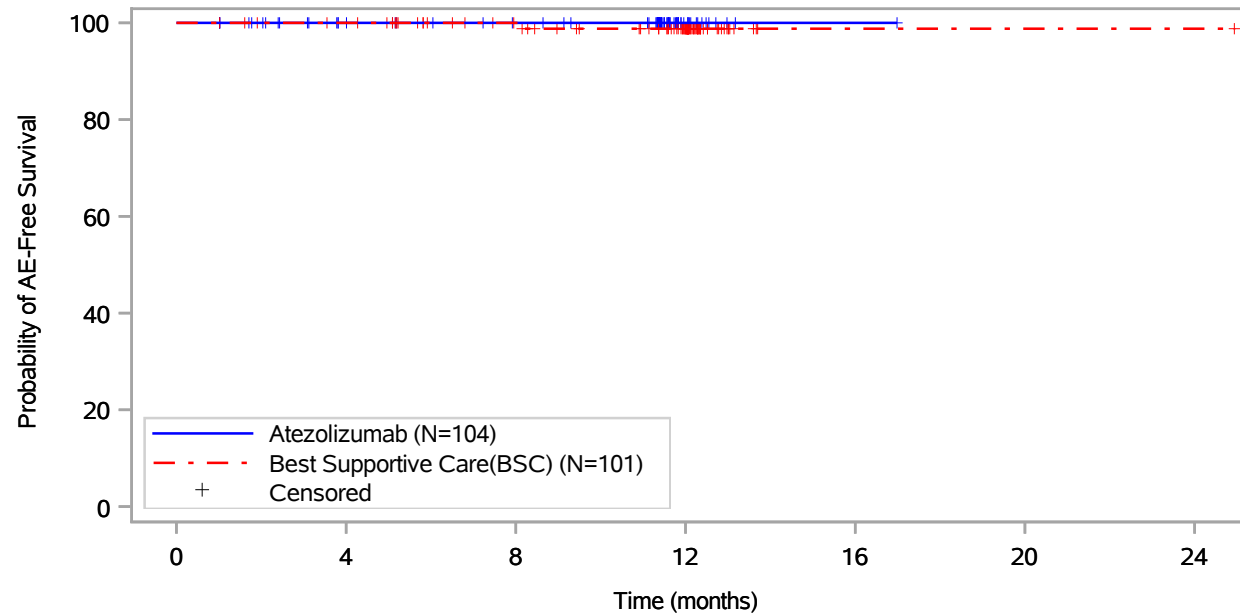
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Micturition disorder



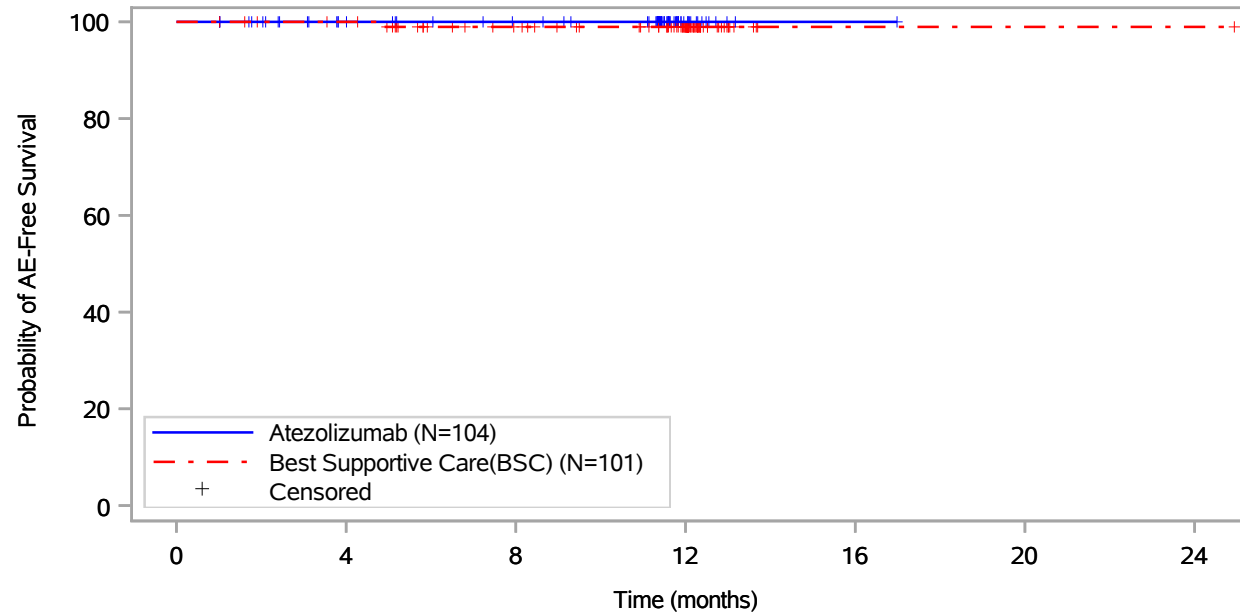
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Renal and urinary disorders, Pollakiuria



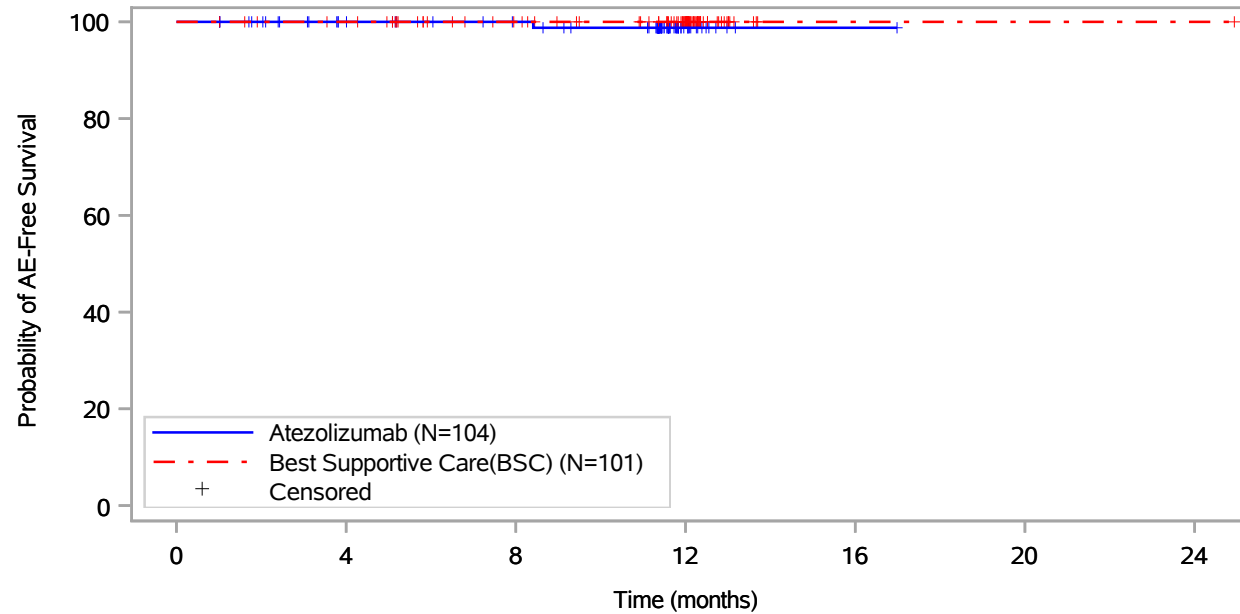
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Renal and urinary disorders, Proteinuria



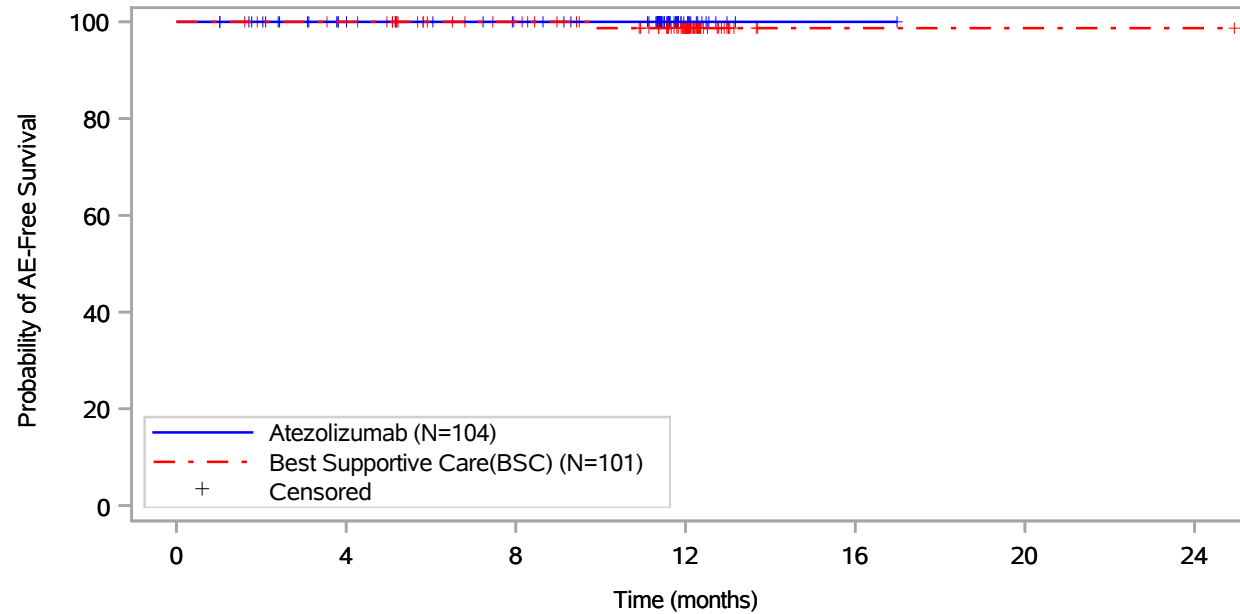
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Renal and urinary disorders, Renal cyst



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

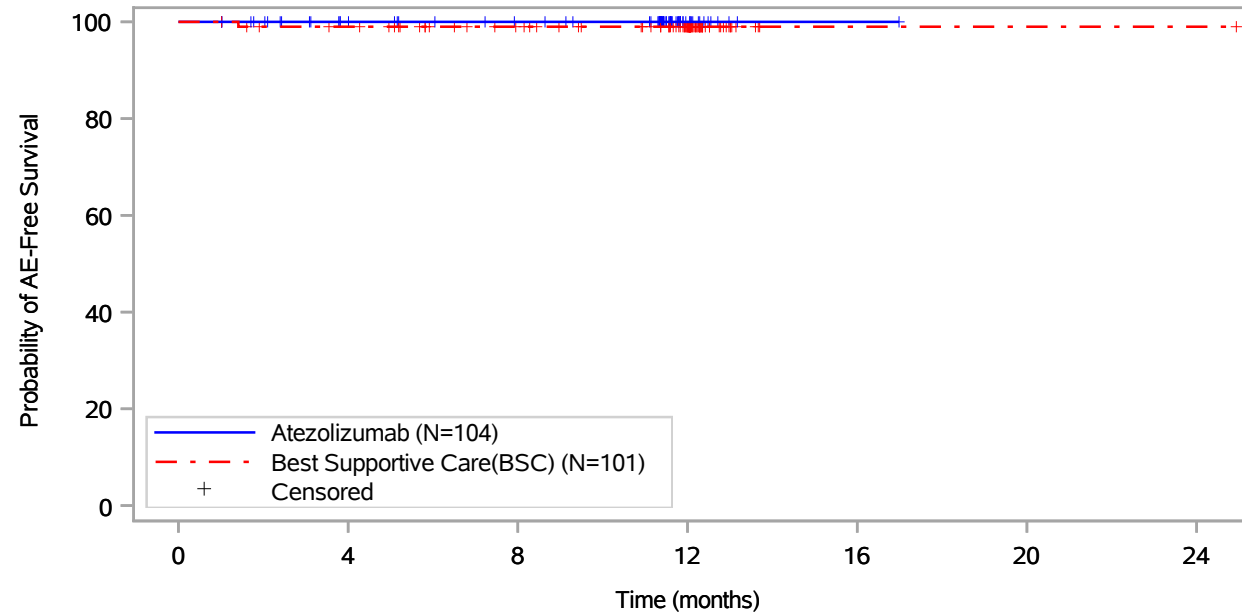
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Renal impairment



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	45	99	99	99

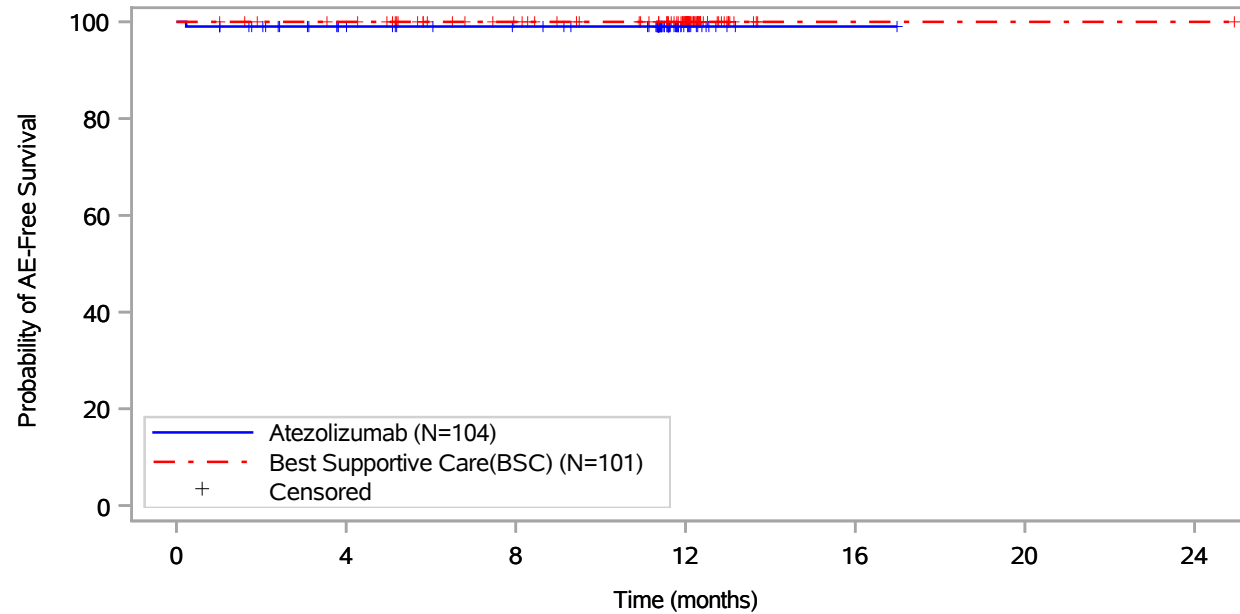
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Renal and urinary disorders, Urinary tract pain



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

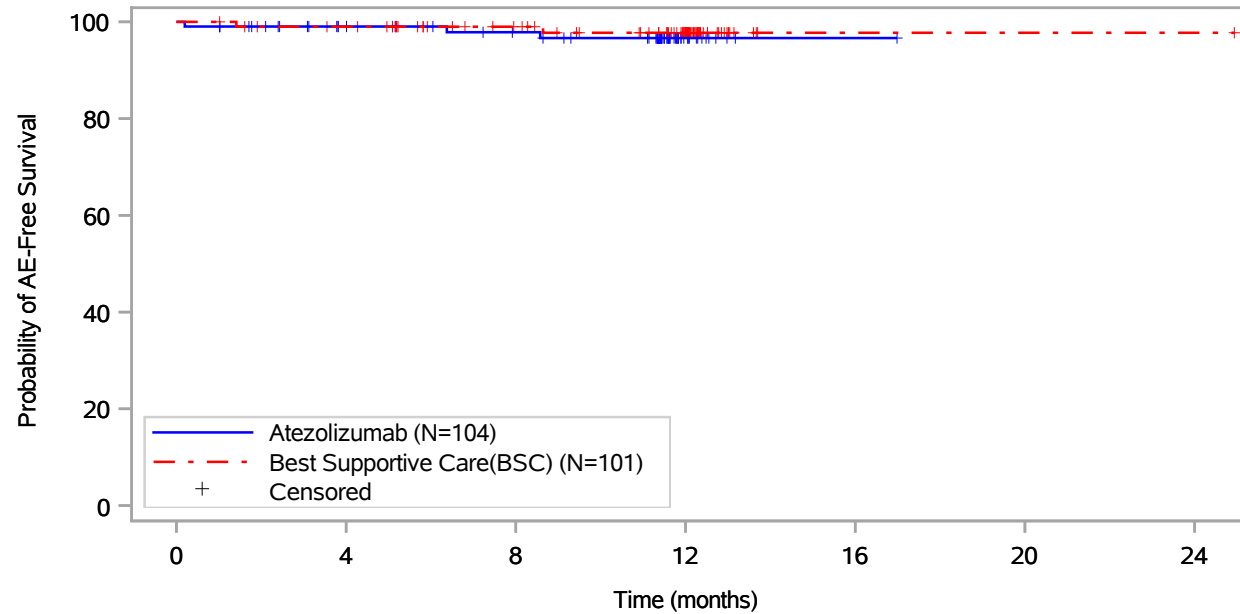
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	88	100	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98	98

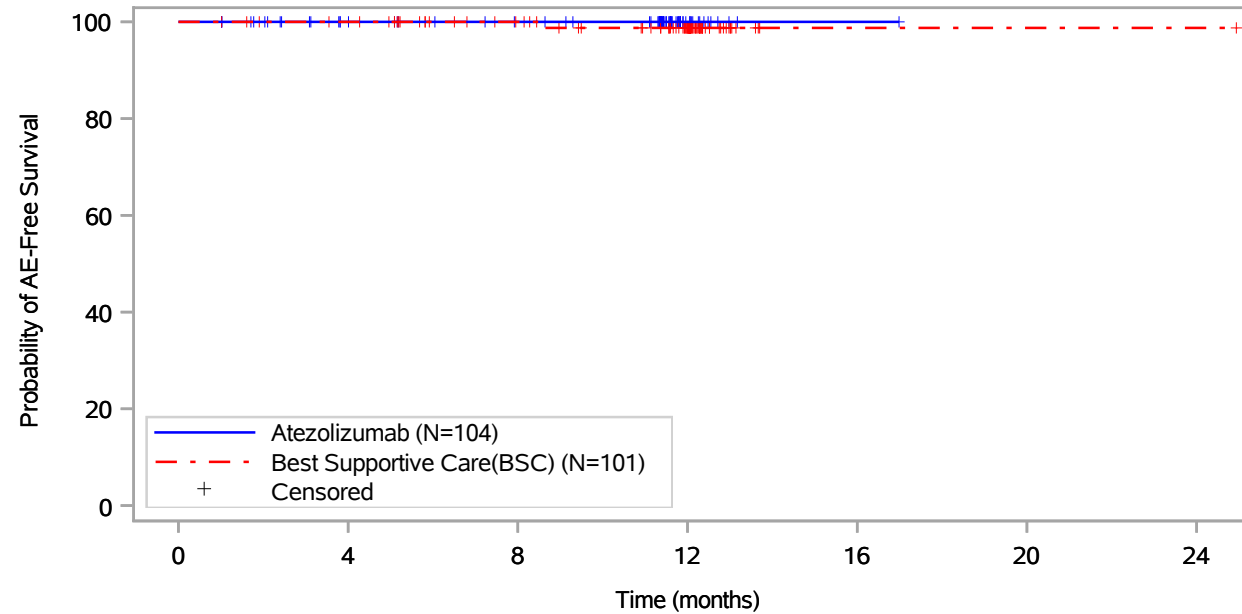
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Balanoposthitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

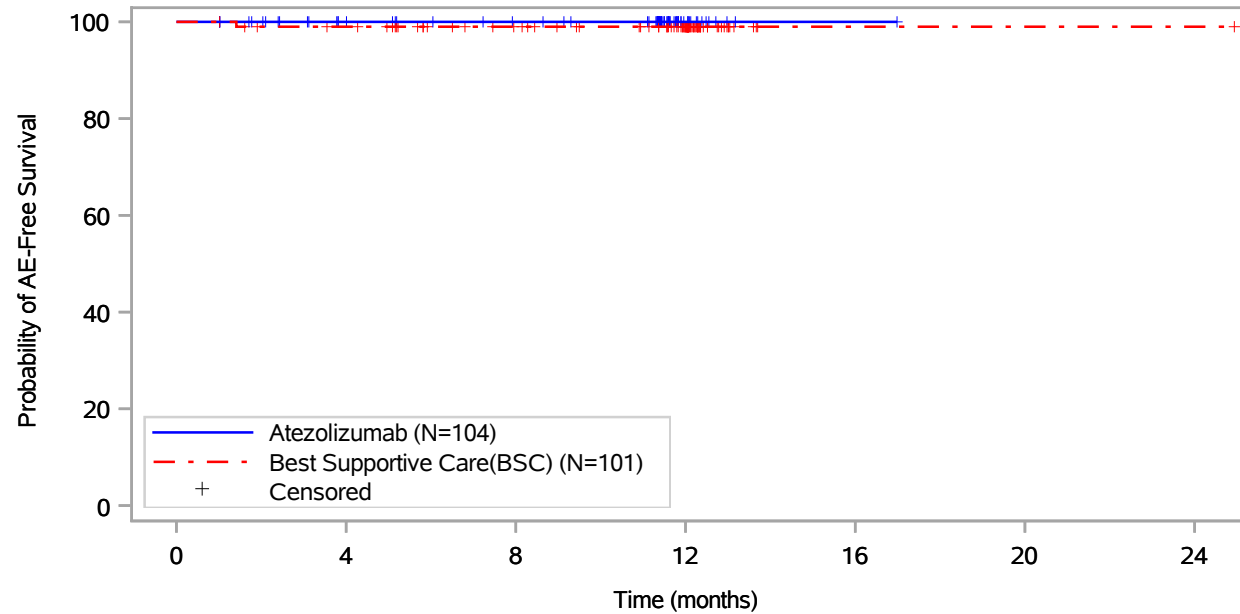
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Breast discharge



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

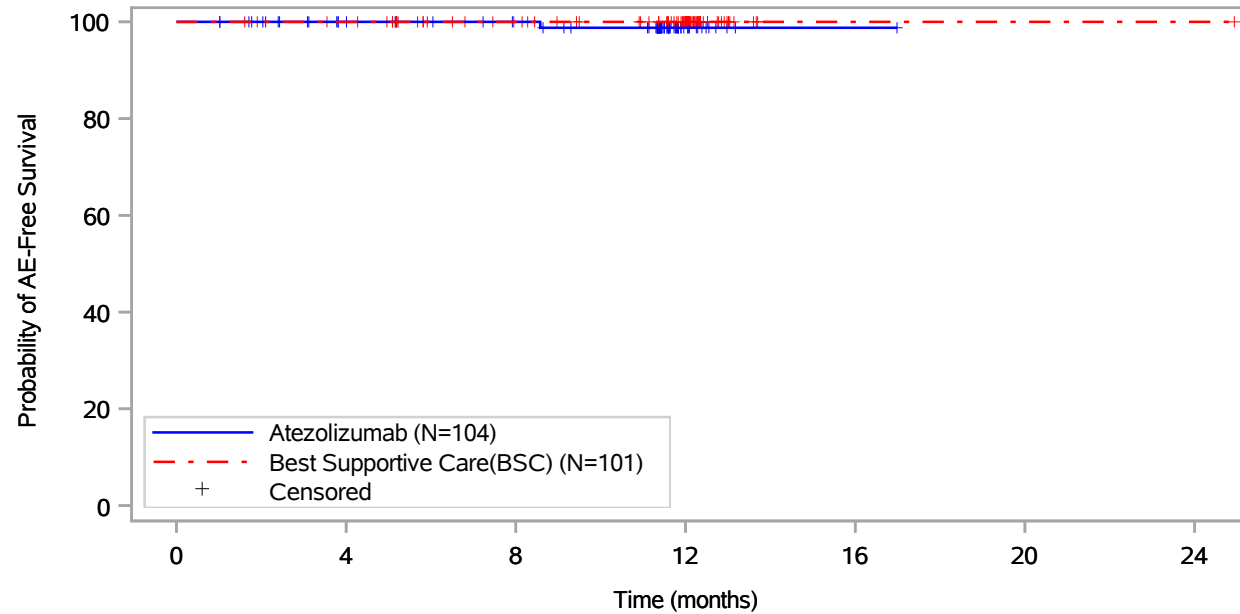
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Breast pain



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

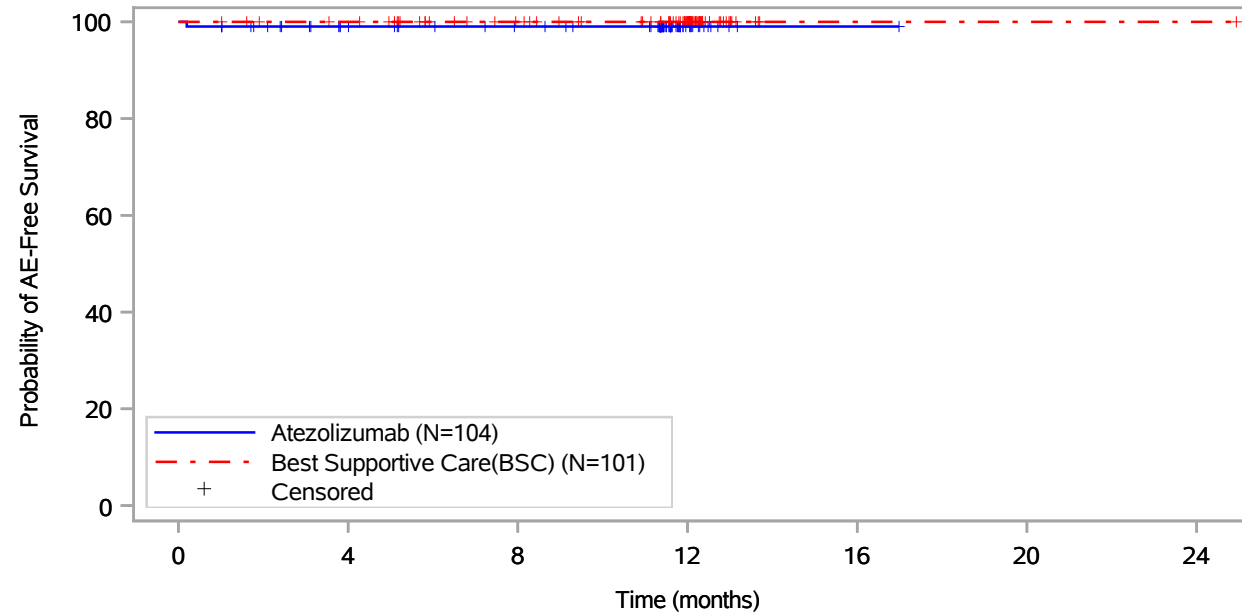
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

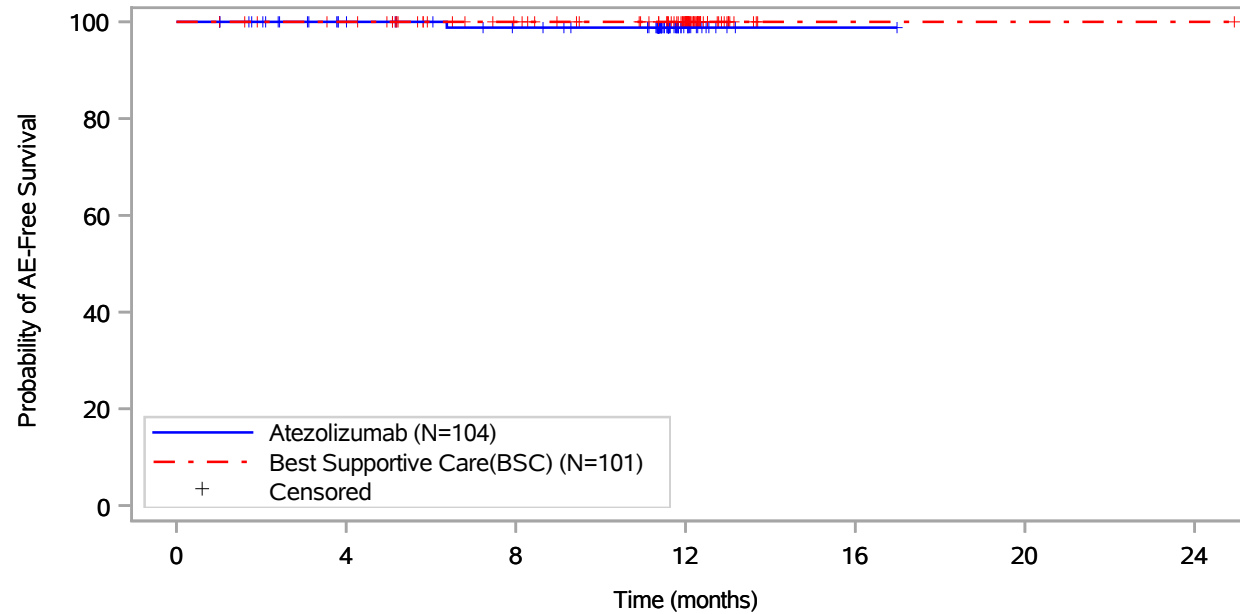
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Gynaecomastia



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

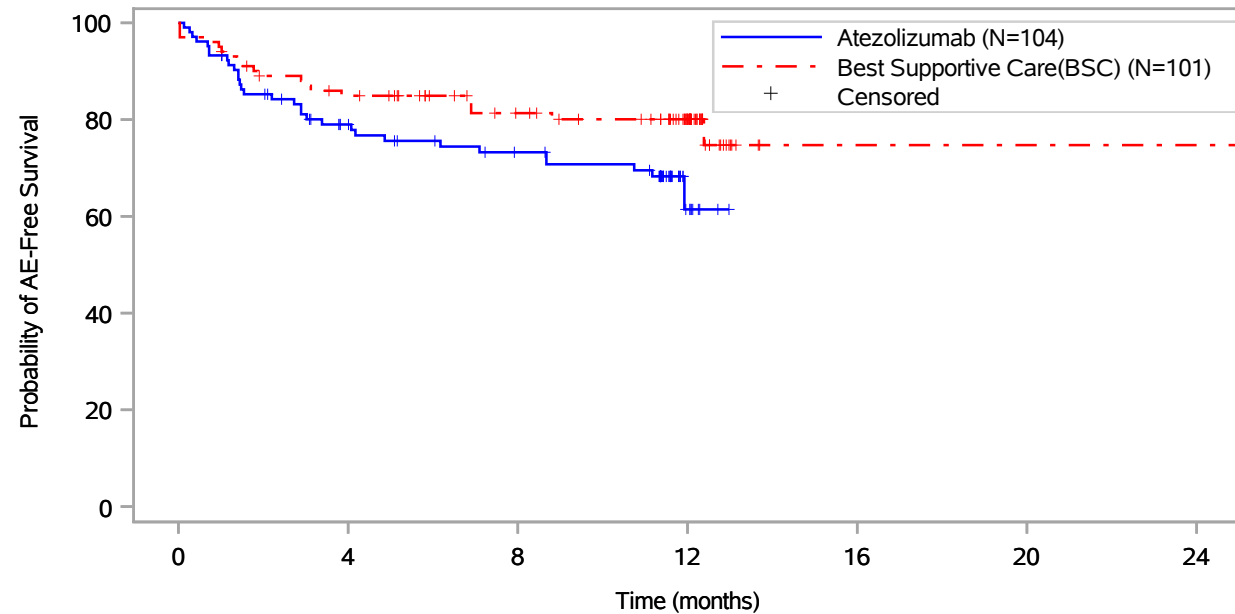
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	71	60	8	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	82	66	41	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	12	18	65	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	41	80	80	80

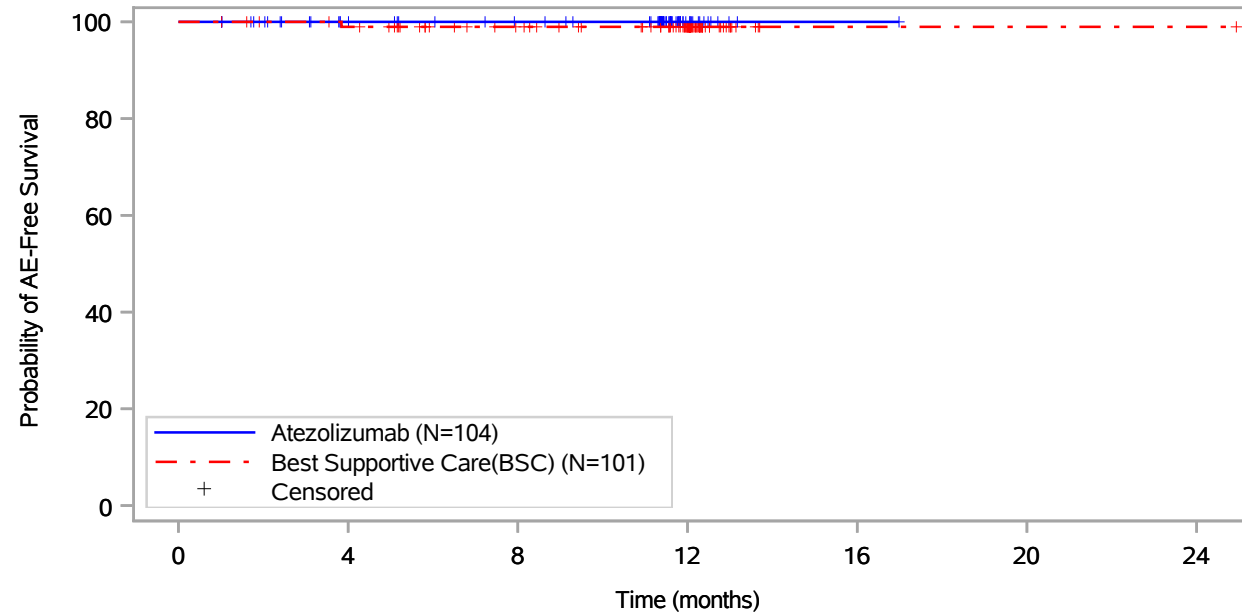
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Catarrh



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

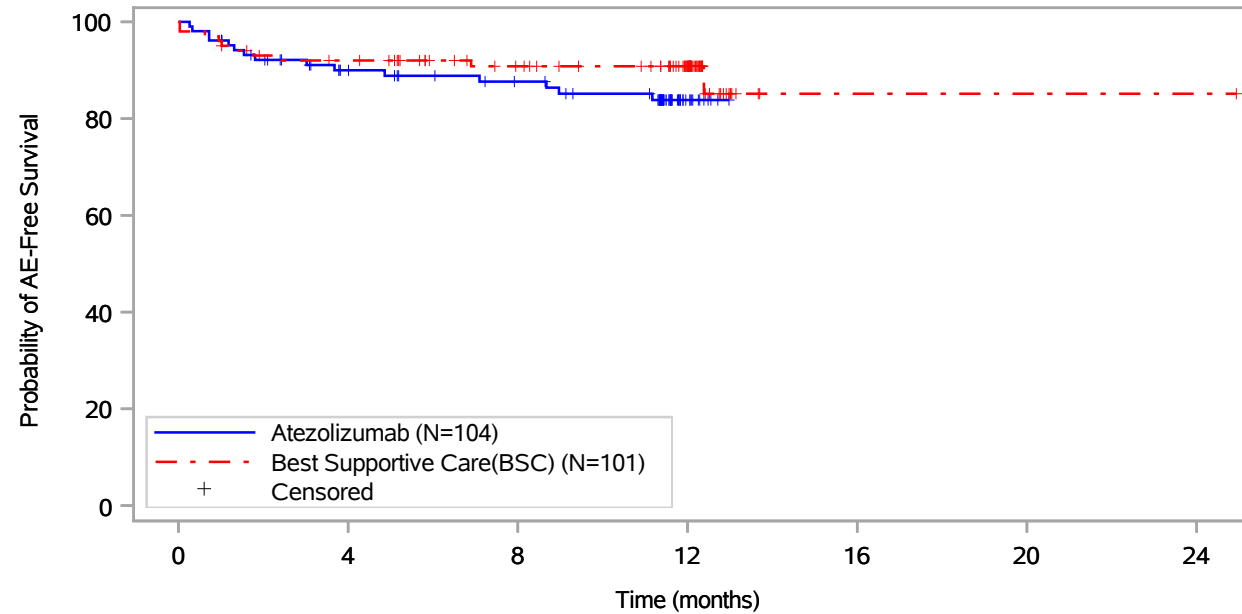
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Cough



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	80	71	11	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	89	74	49	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	78	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	43	90	90	90

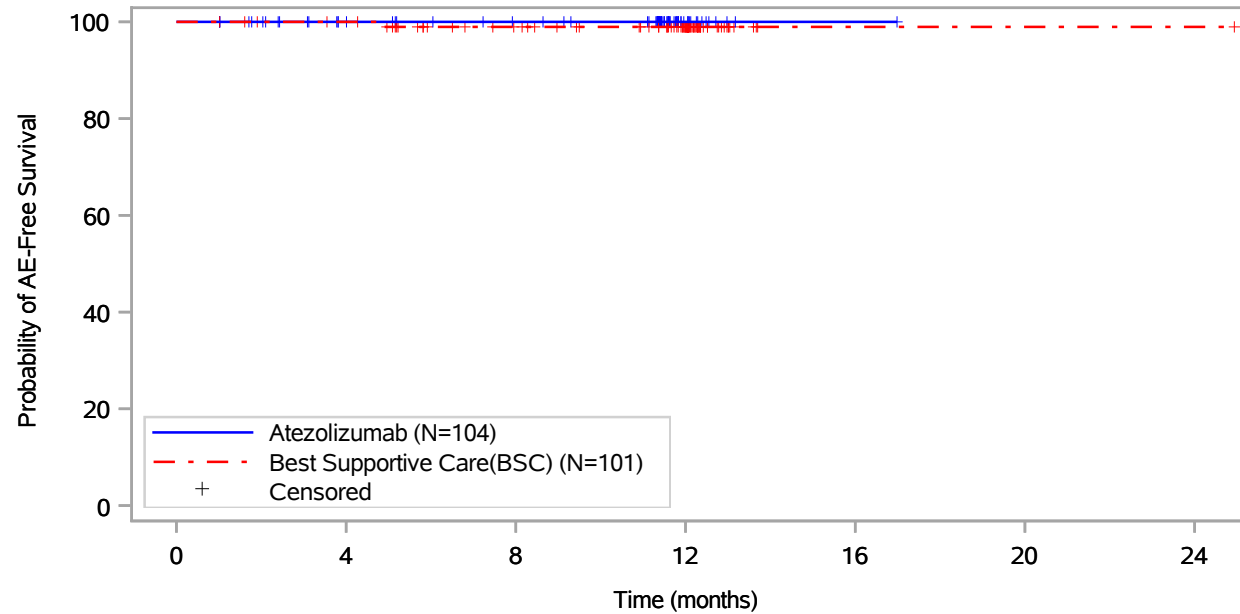
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dysphonia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

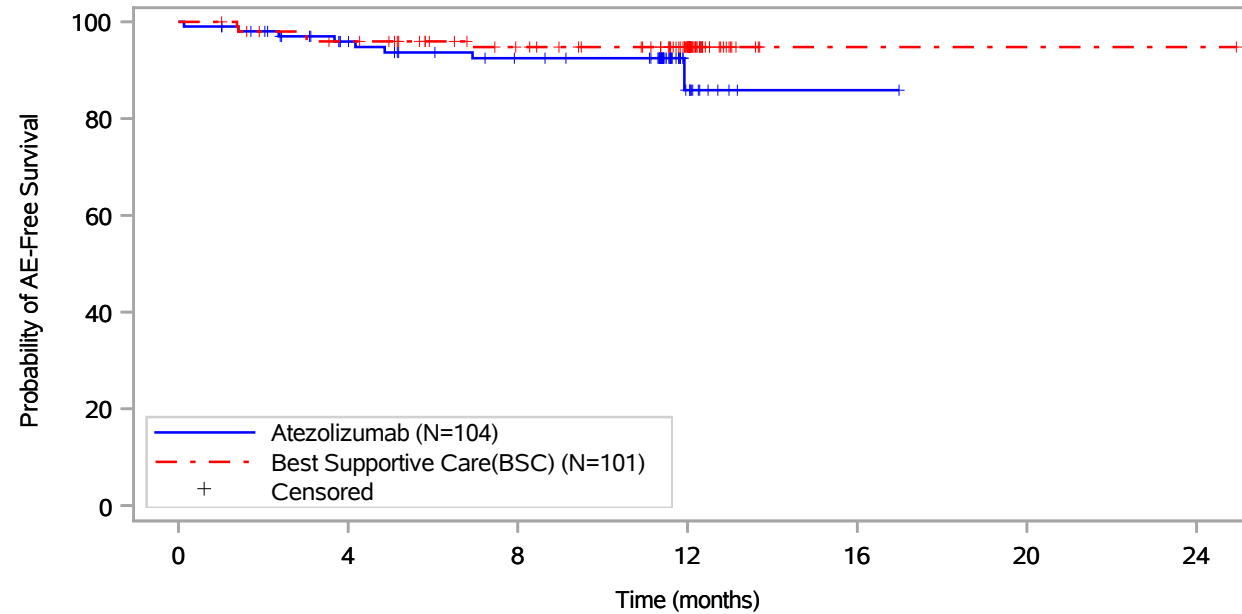
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk							
Atezolizumab (N=104)	104	86	76	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	93	79	52	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	84	95	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	95	95	95

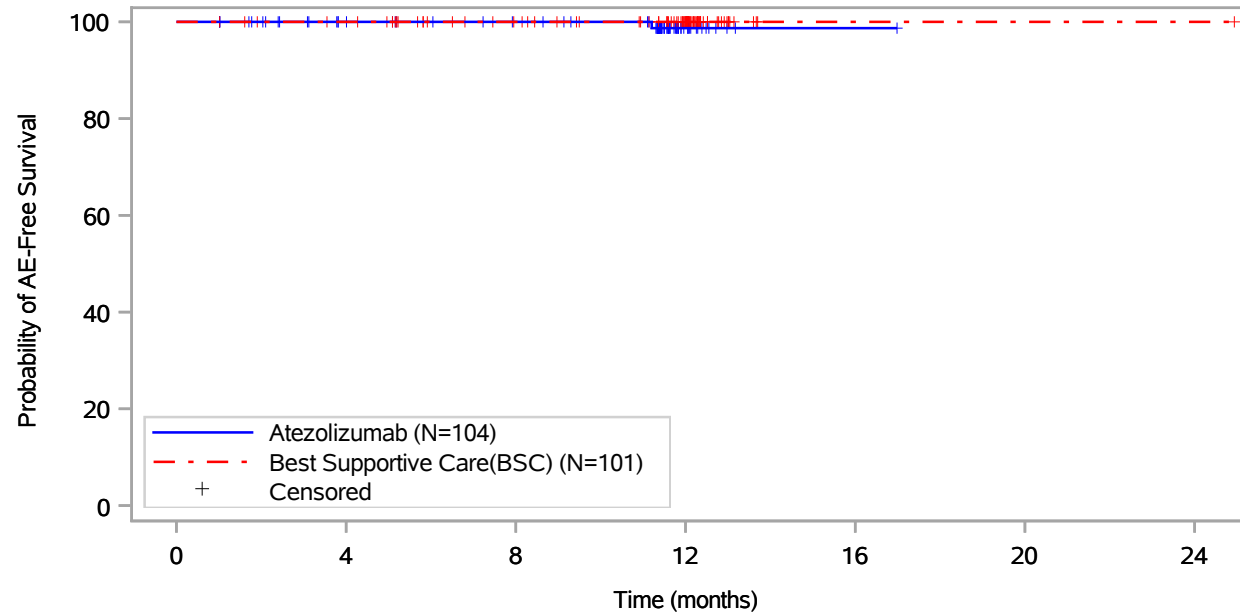
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Haemoptysis



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

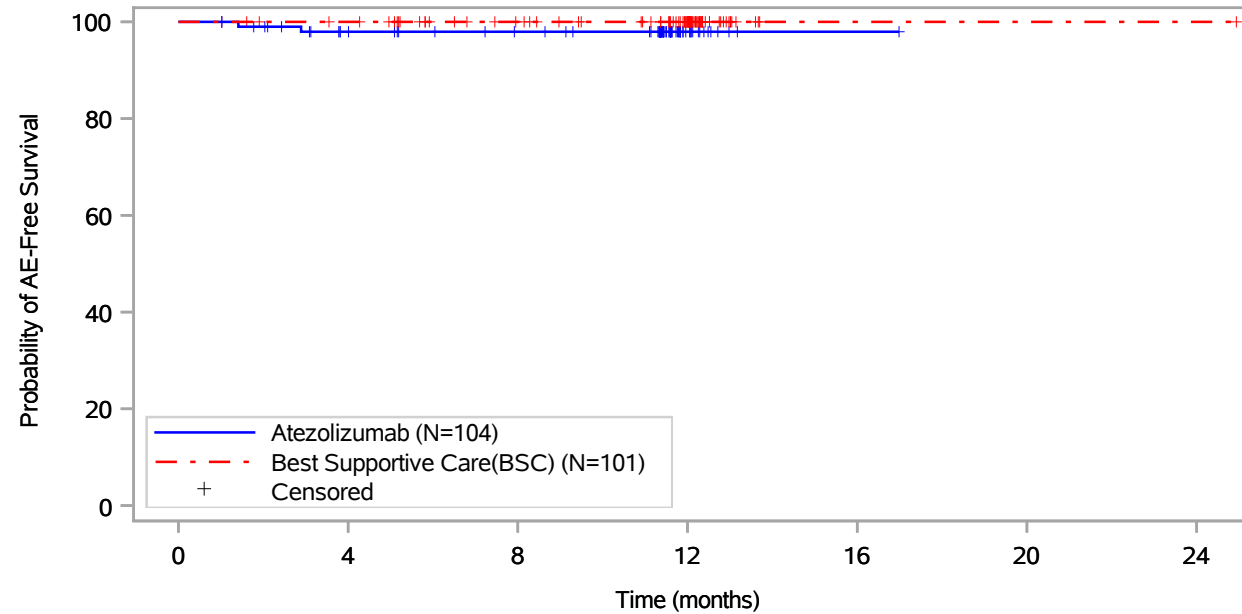
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	13	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

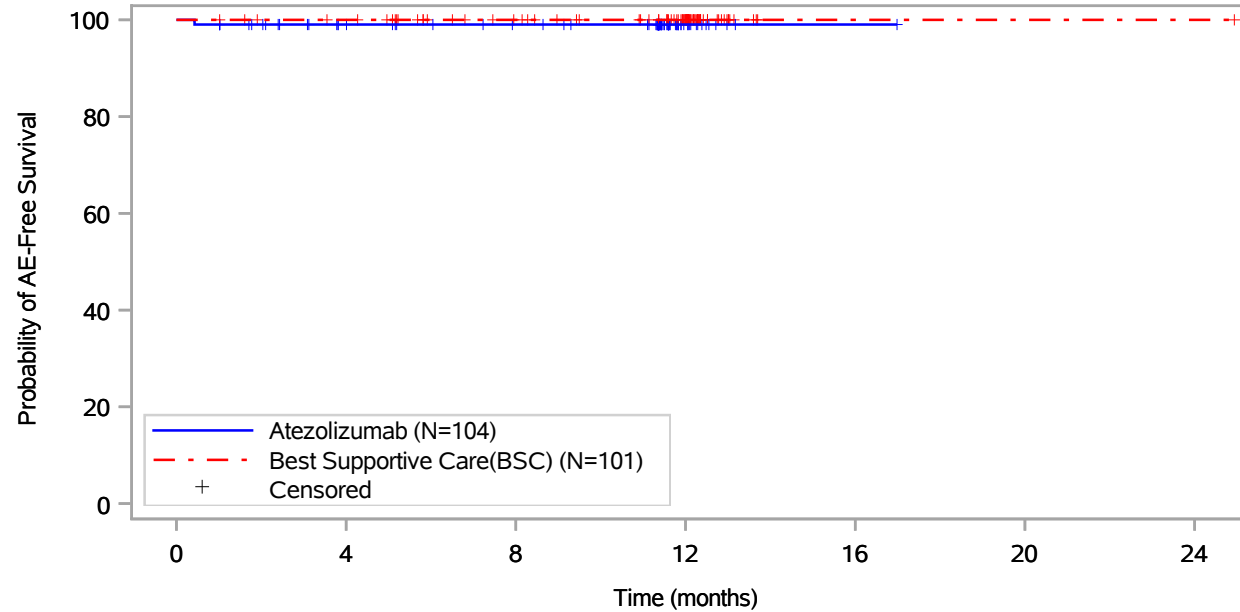
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Laryngospasm



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

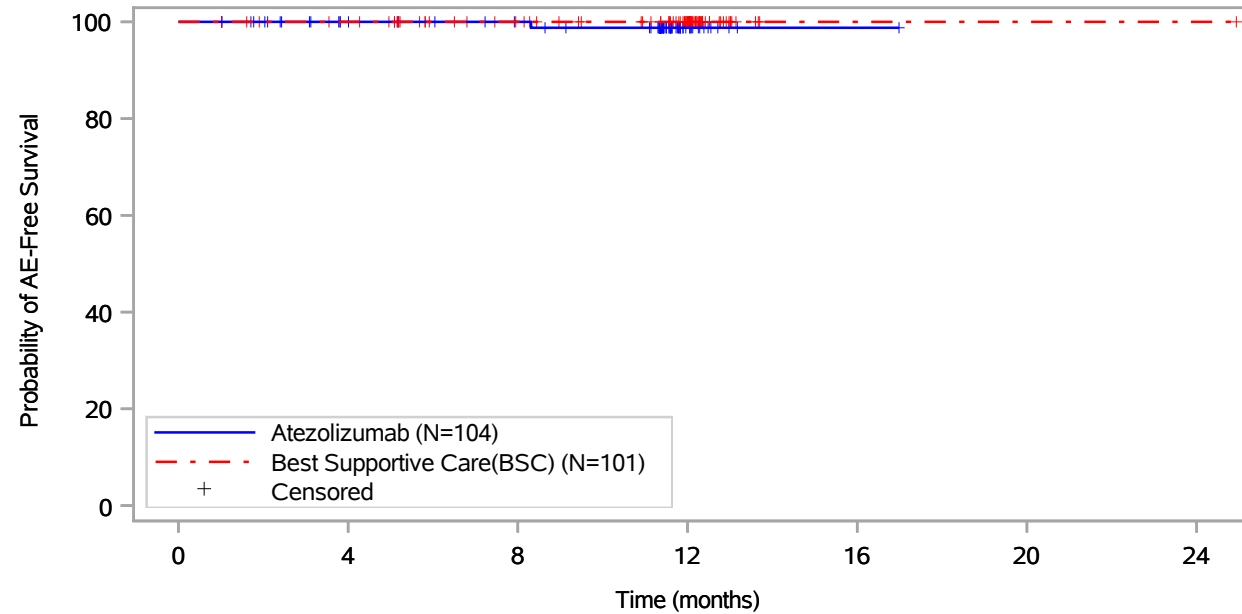
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Lung disorder



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

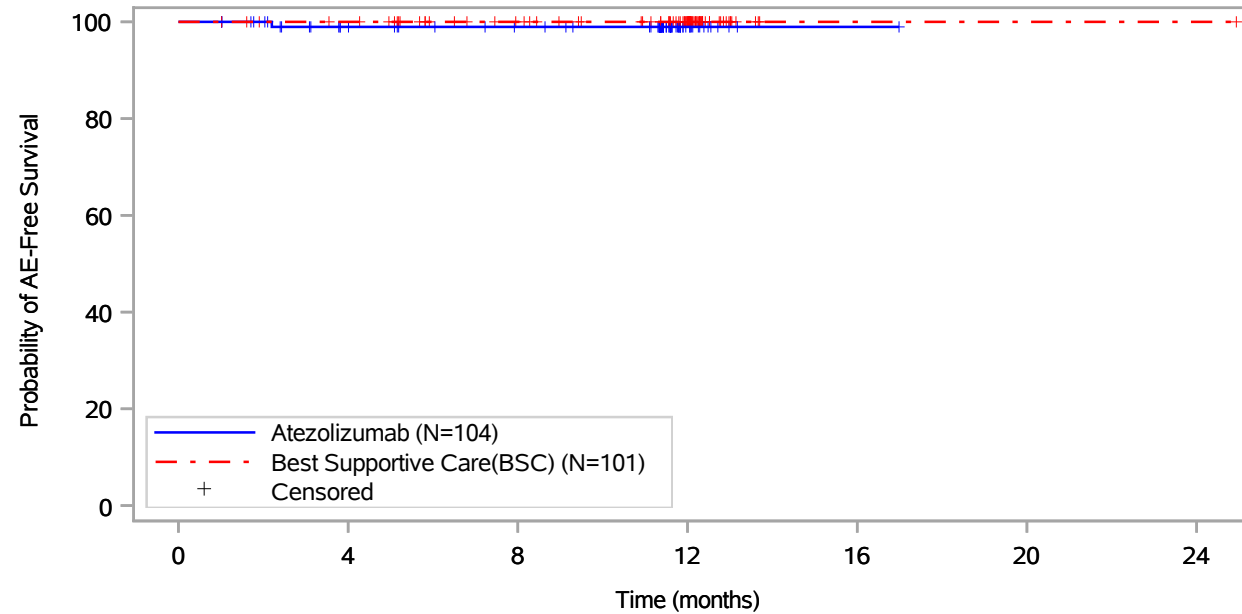
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Nasal congestion



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

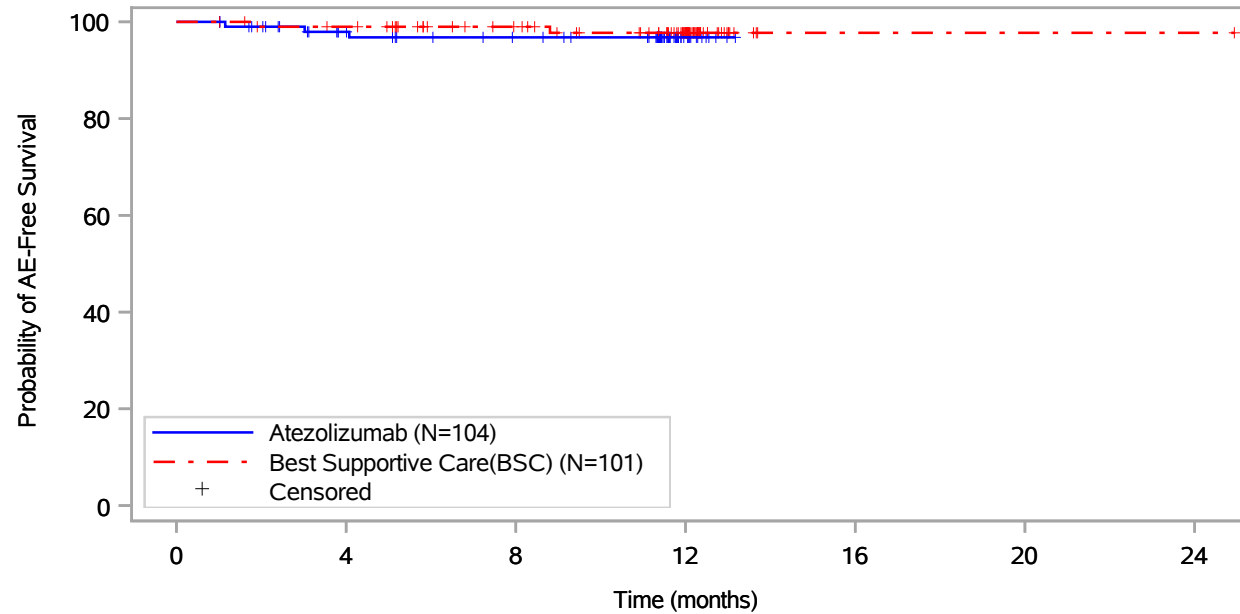
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Oropharyngeal pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	87	79	13	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	53	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	88	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	98	98	98

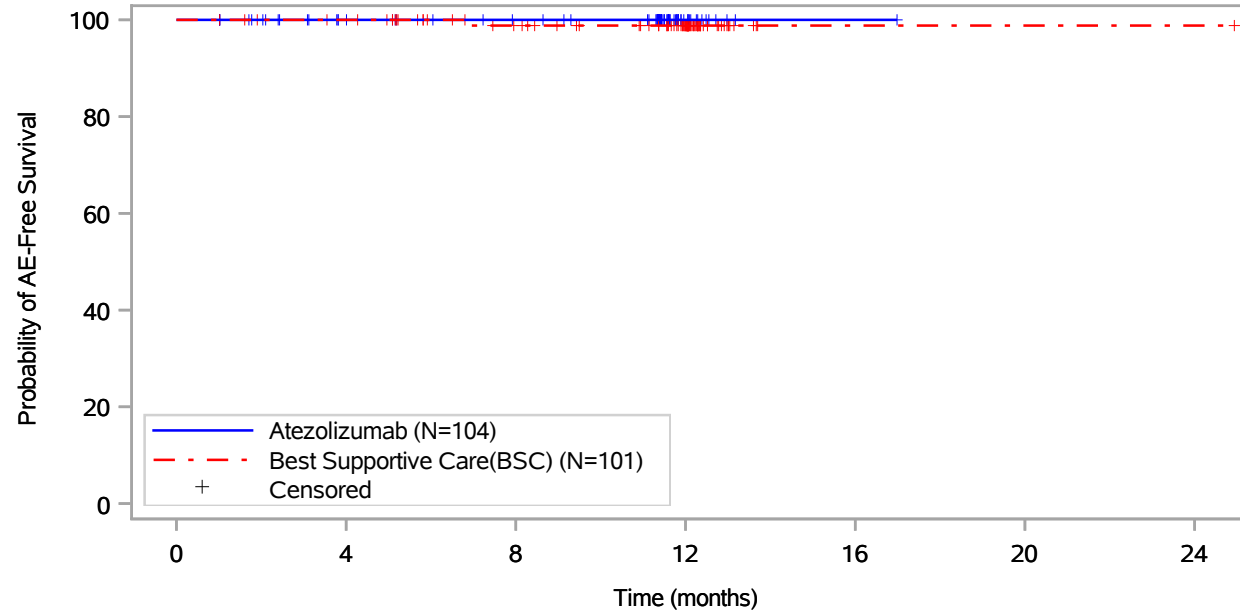
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pleurisy



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

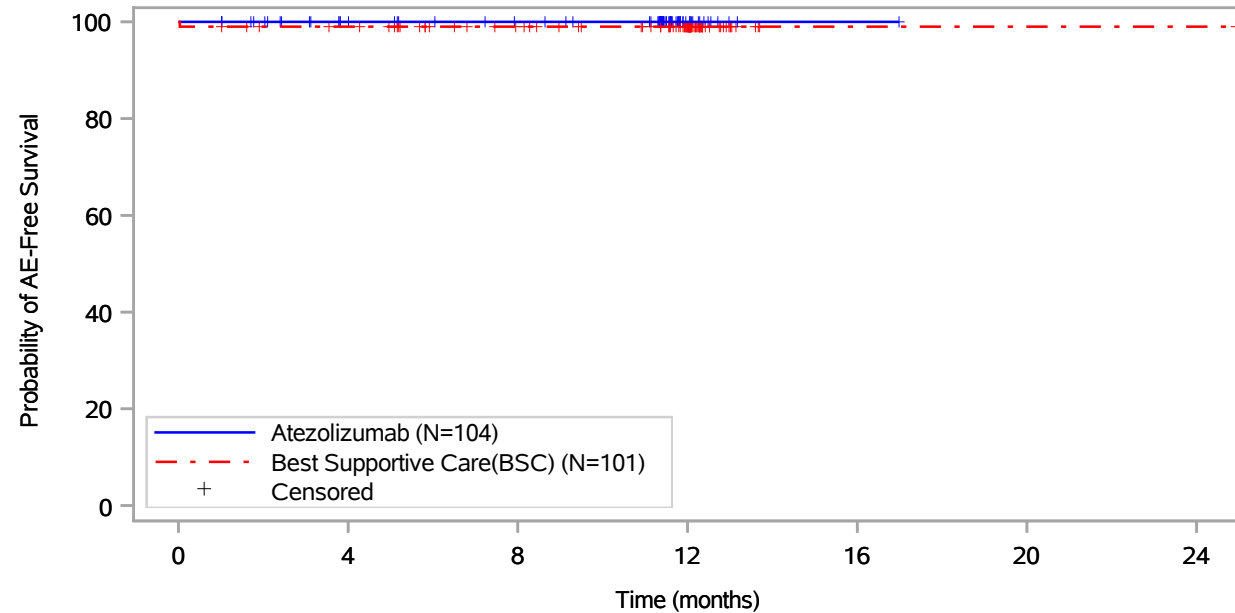
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pleuritic pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	96	82	54	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	99	99	99

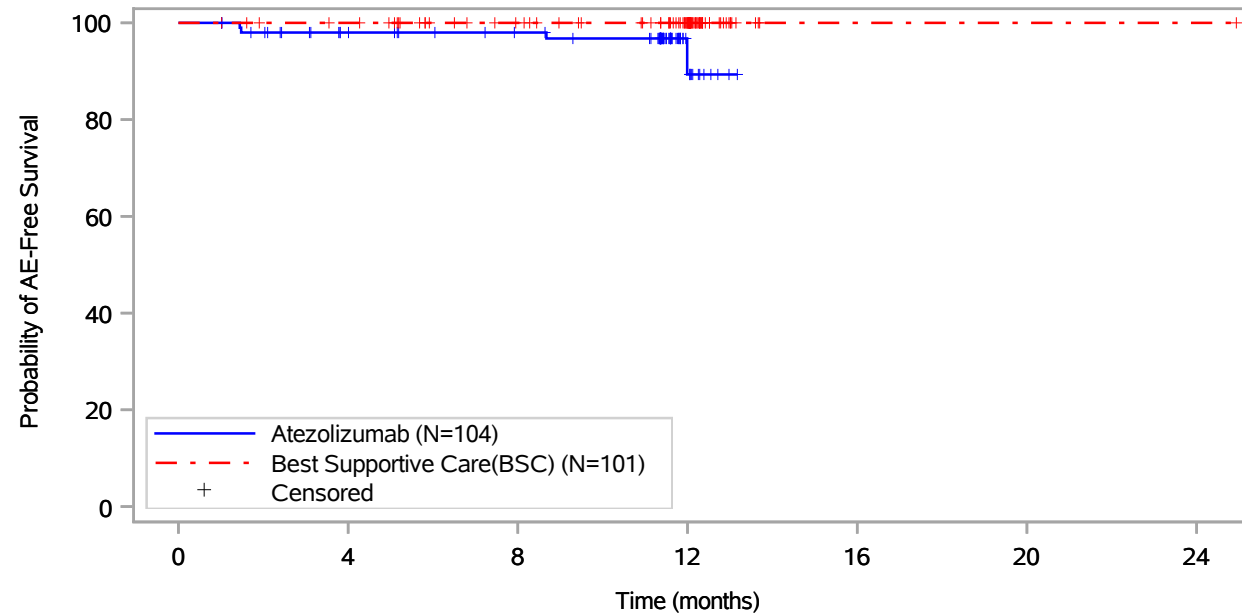
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pneumonitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	12	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	88	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

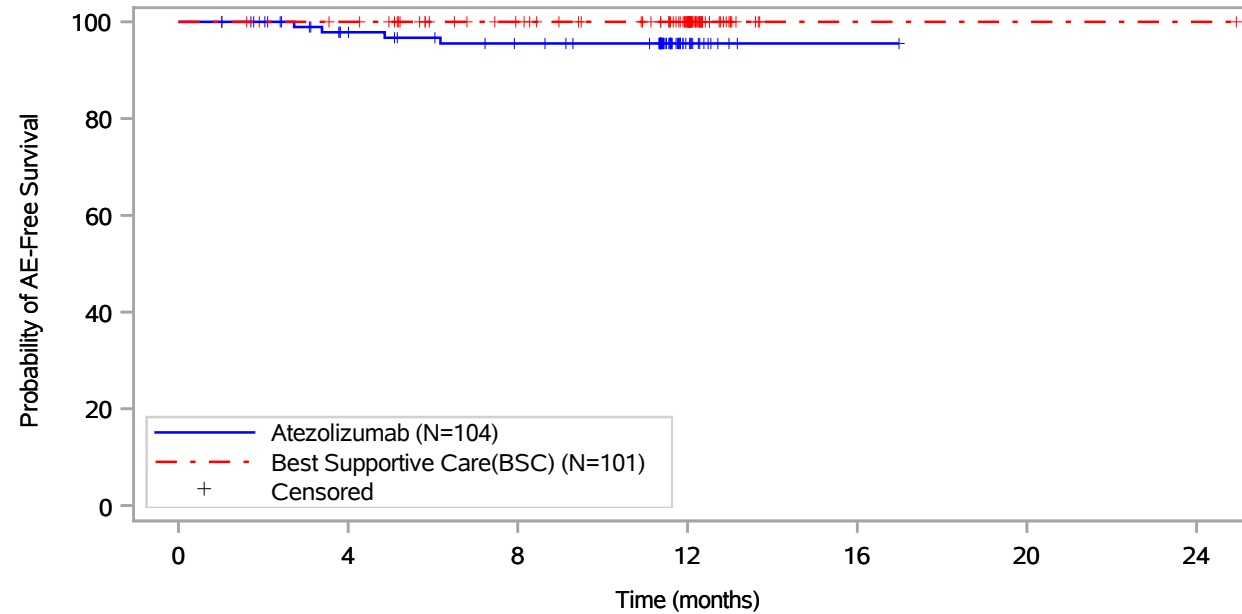
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Productive cough



Patients at risk							
Atezolizumab (N=104)	104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

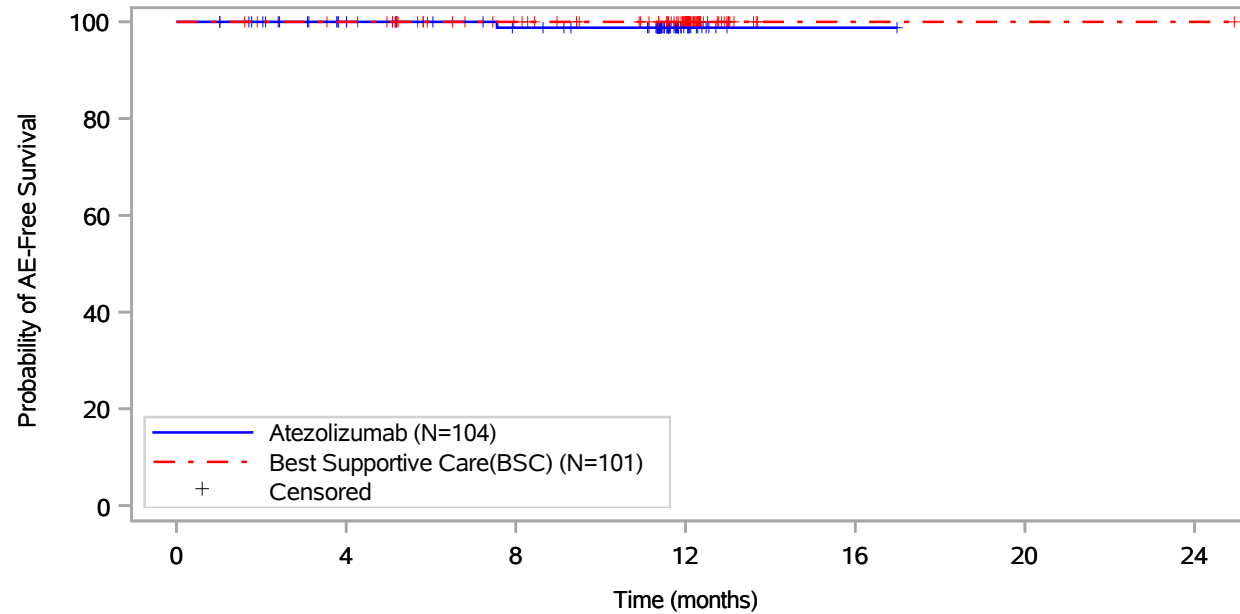
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rales



Patients at risk							
Atezolizumab (N=104)	104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

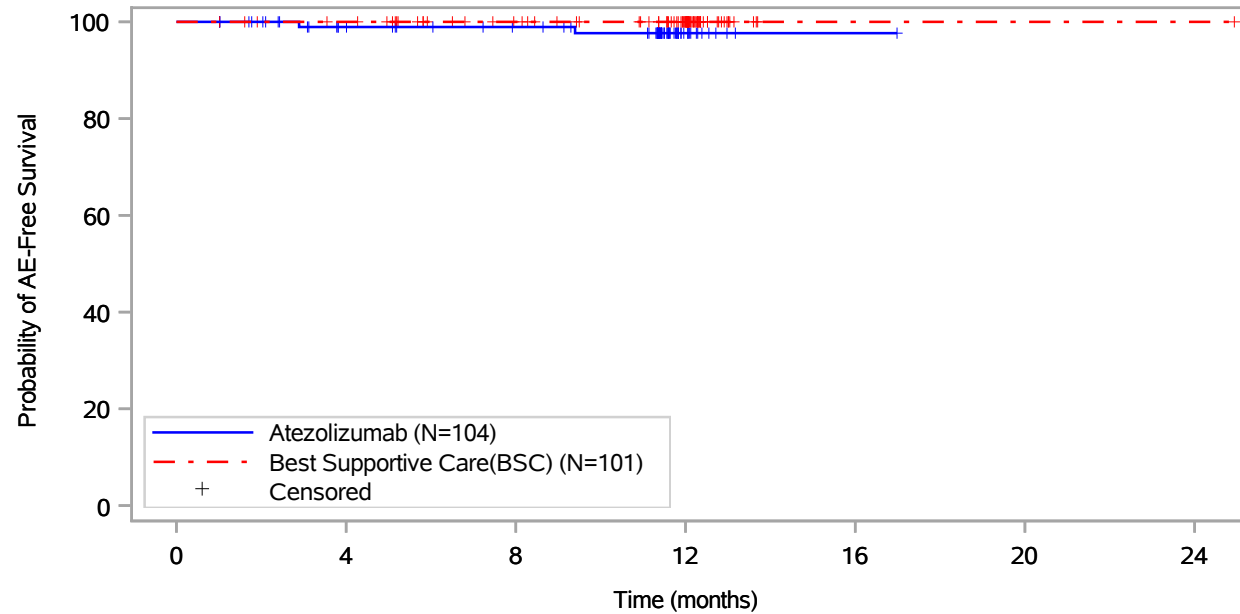
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rhinitis allergica



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

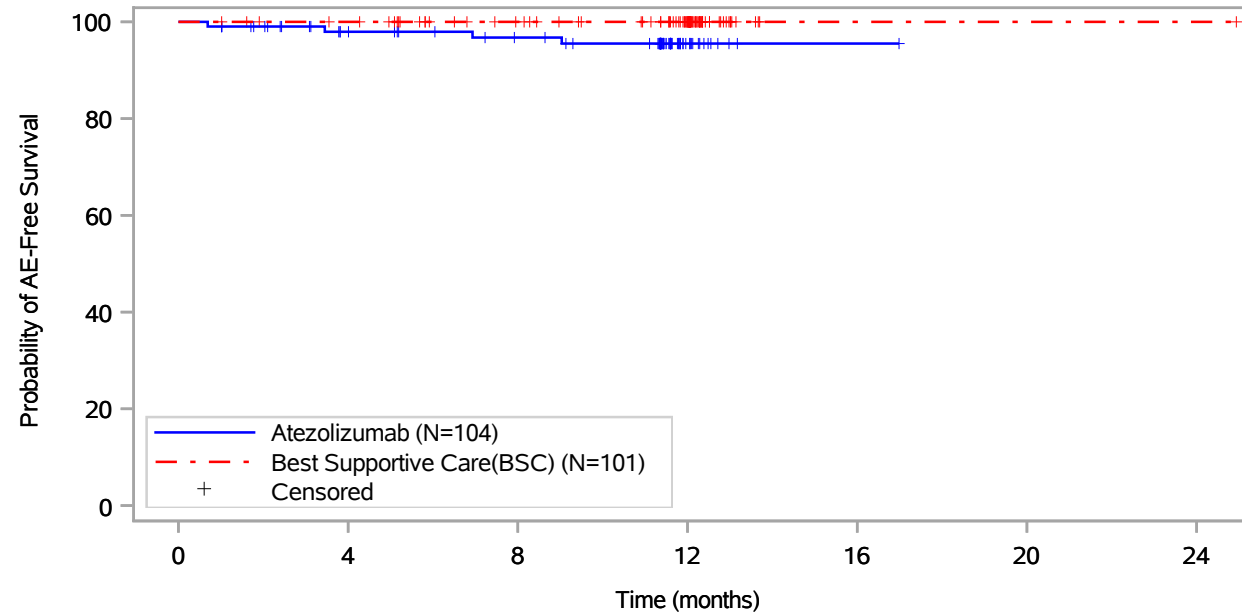
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Rhinorrhoea



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	87	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	86	99	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

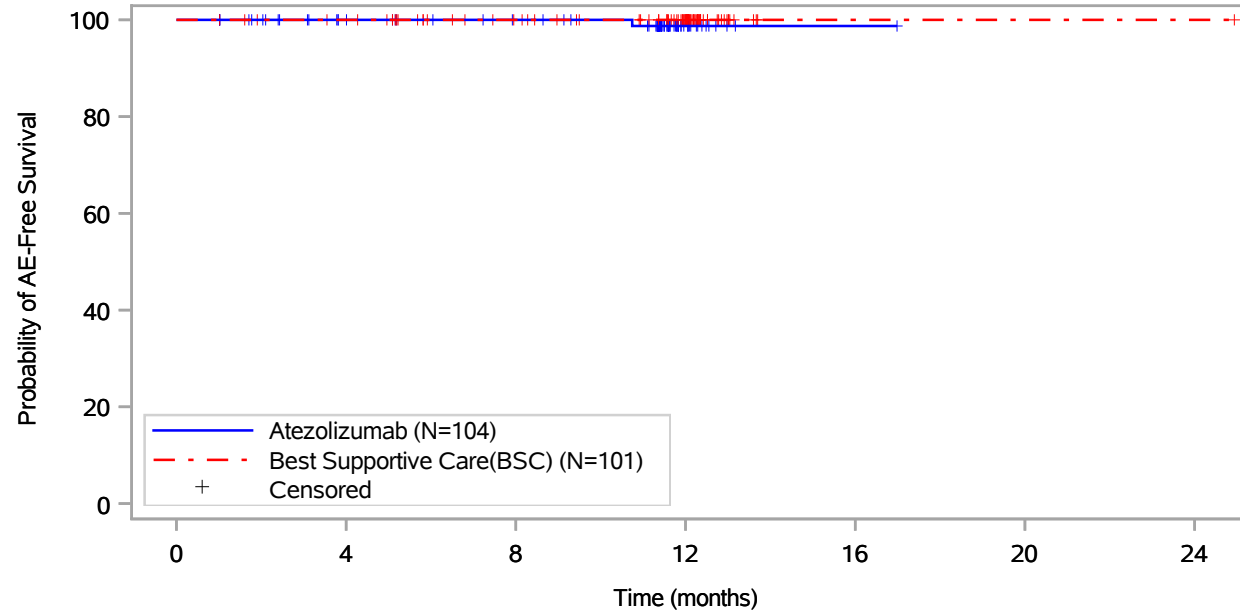
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Sleep apnoea syndrome



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

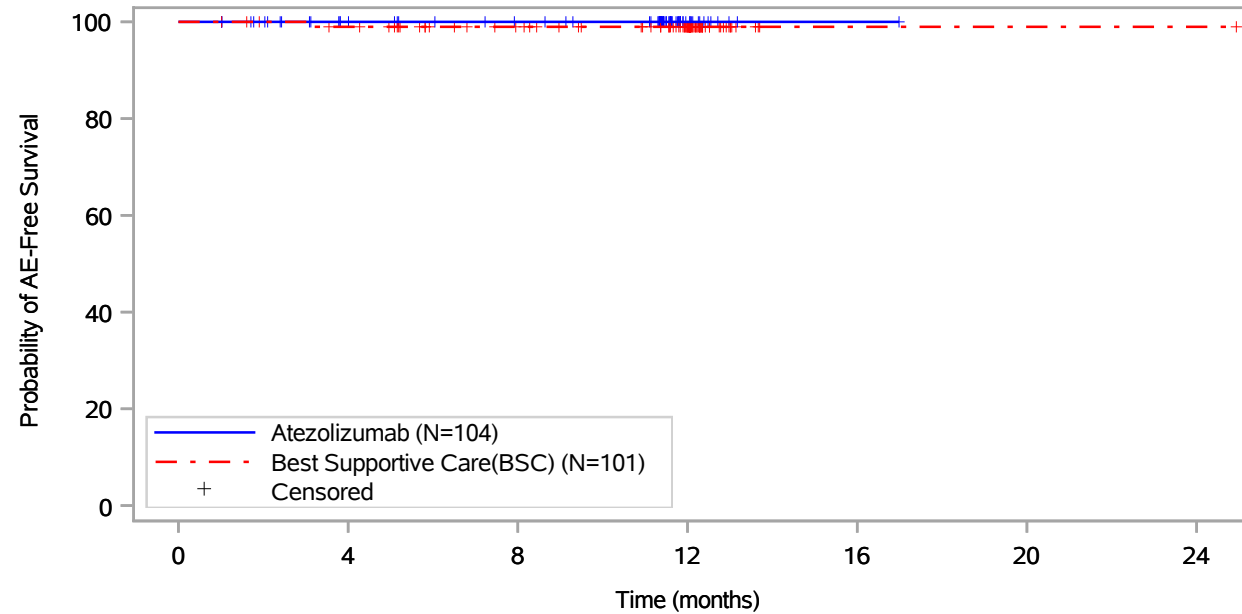
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Upper-airway cough syndrome



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

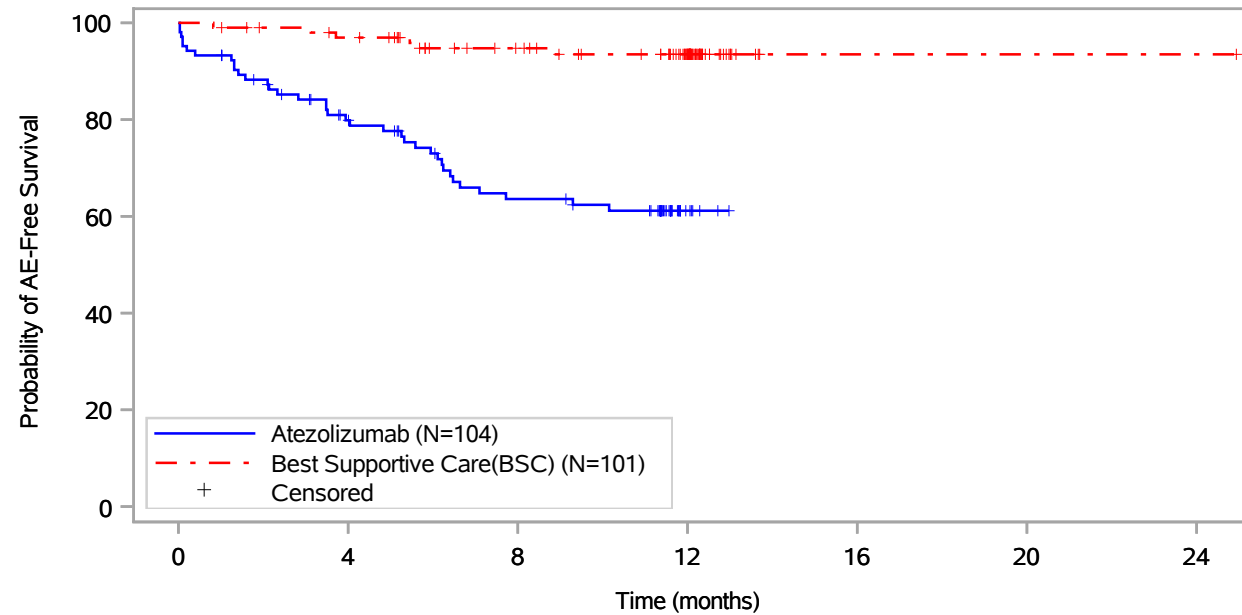
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	73	54	6	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	94	78	51	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	11	16	62	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	44	94	94	94

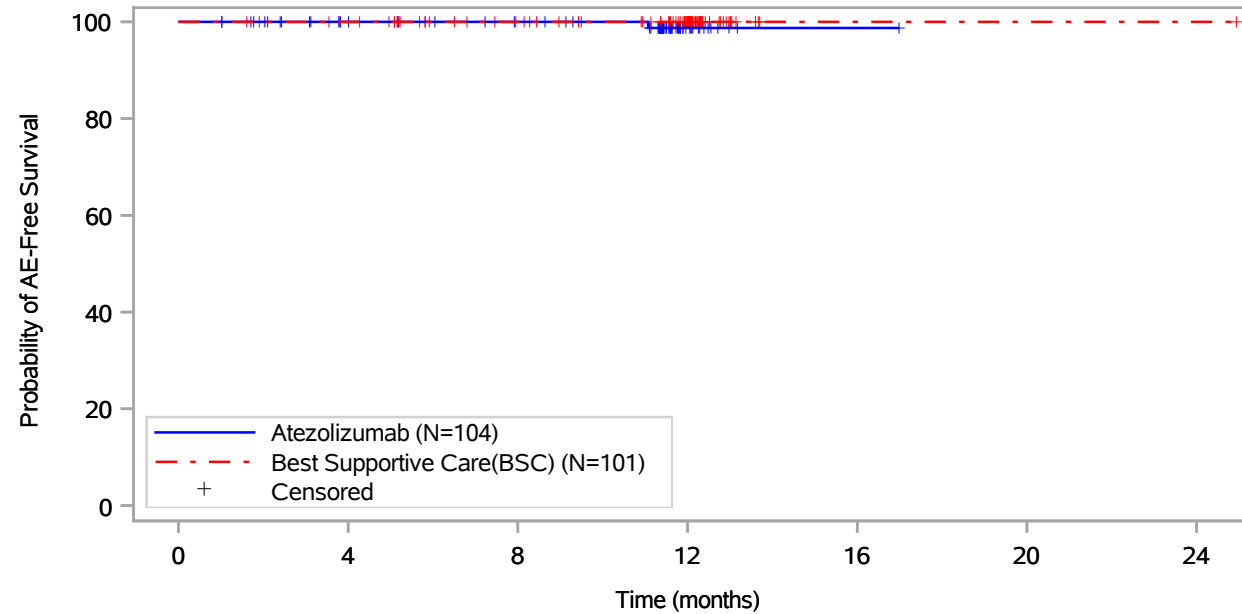
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Actinic keratosis



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

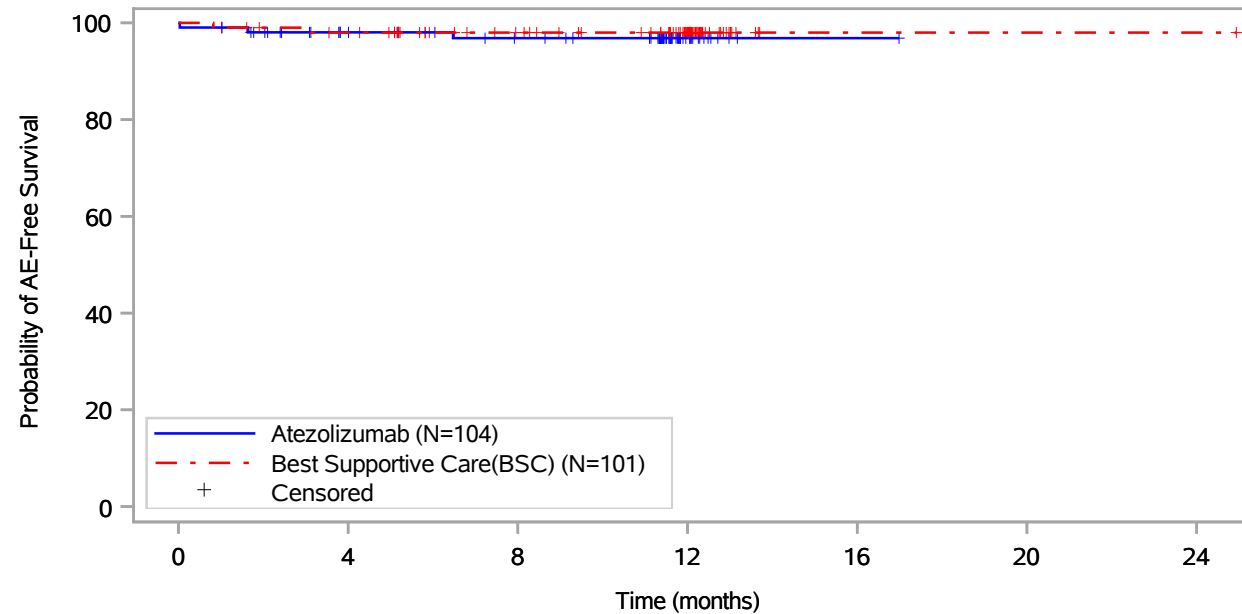
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Alopecia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	87	79	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	87	100	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98	98

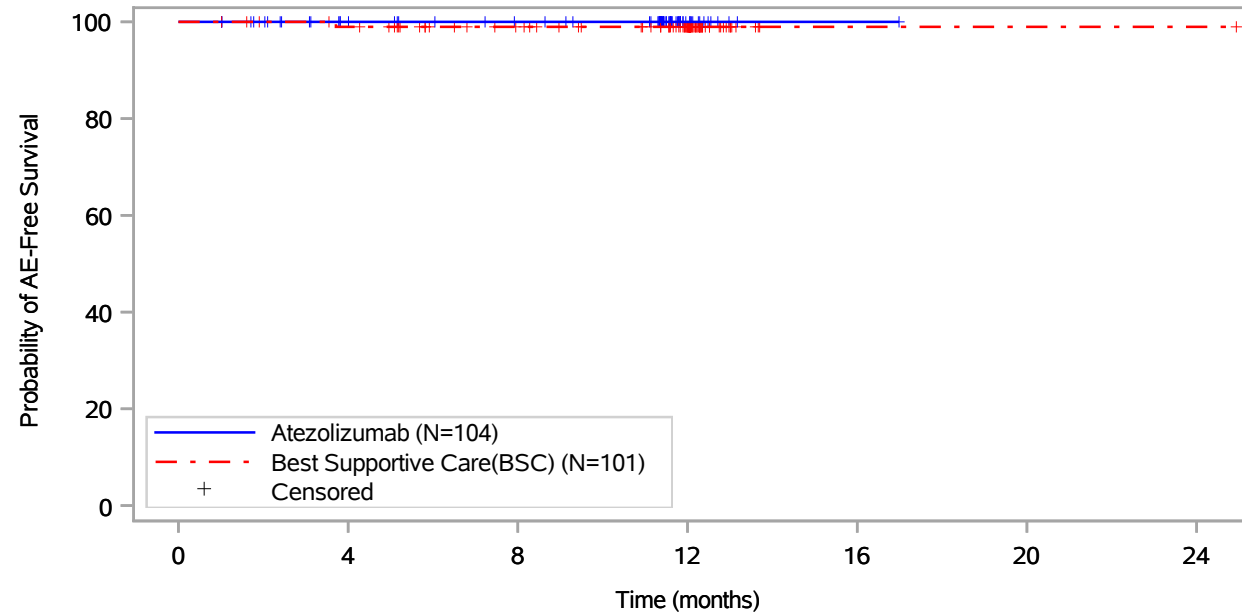
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

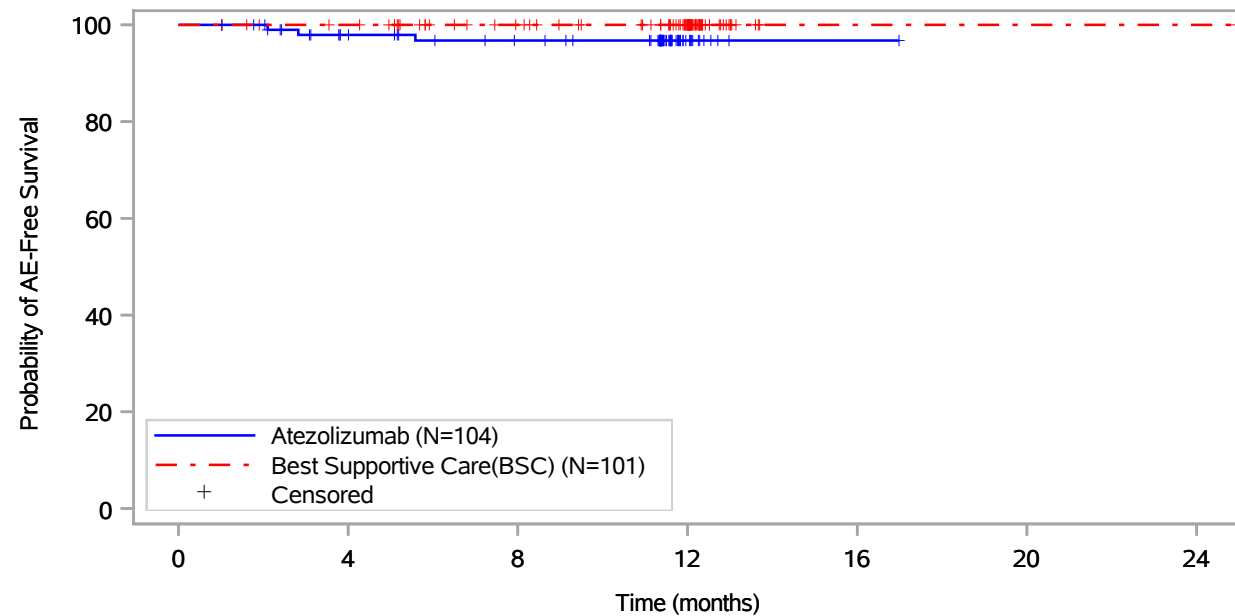
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis acneiform



Patients at risk							
Atezolizumab (N=104)	104	88	80	12	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

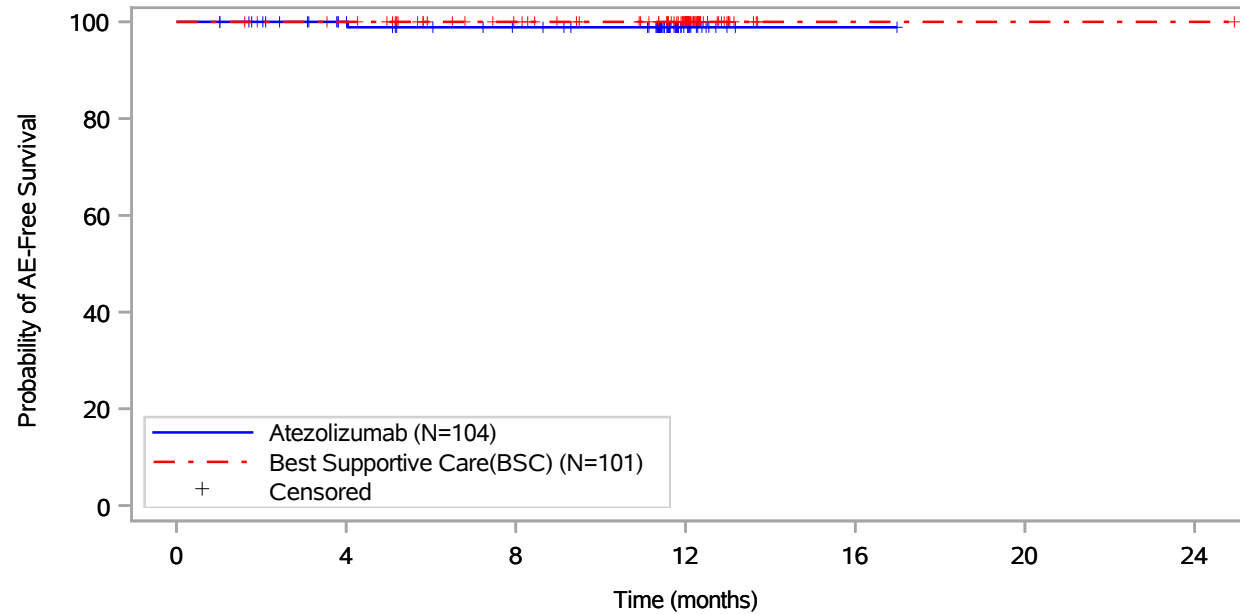
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Dermatitis exfoliative



Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

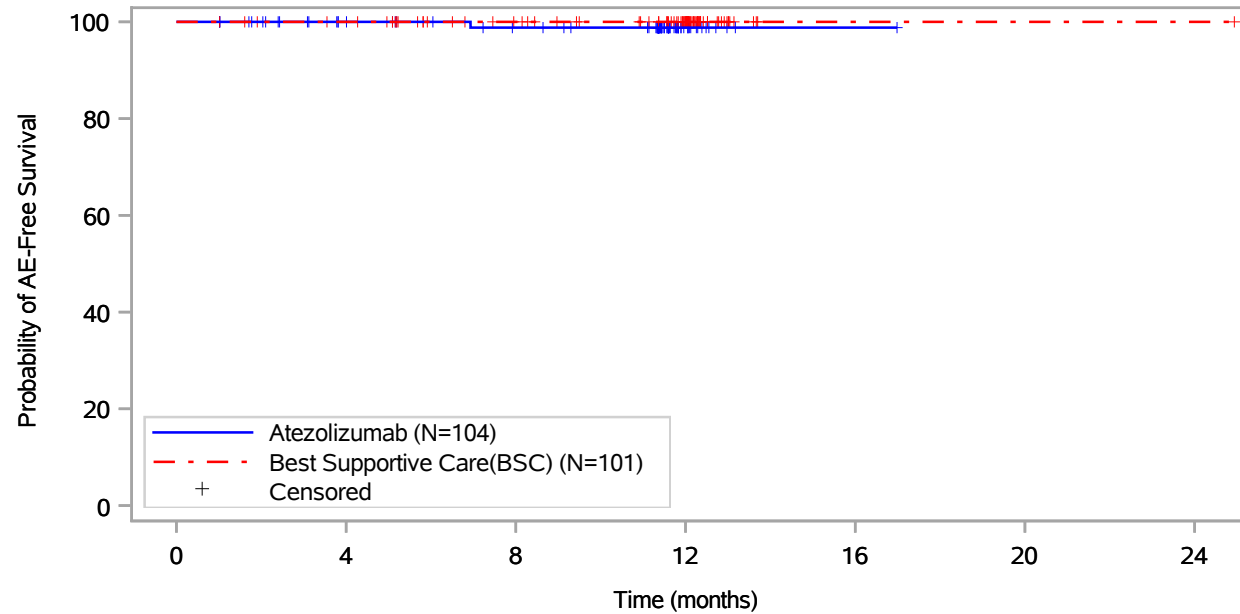
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Drug eruption



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

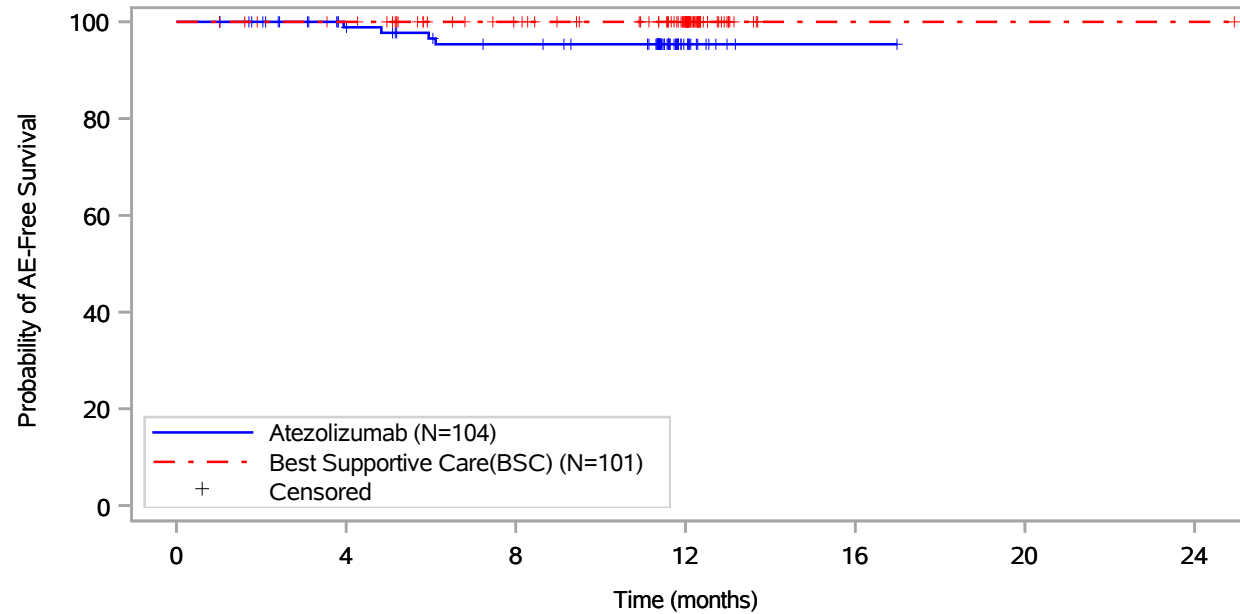
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Dry skin



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	79	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	21	87	99	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

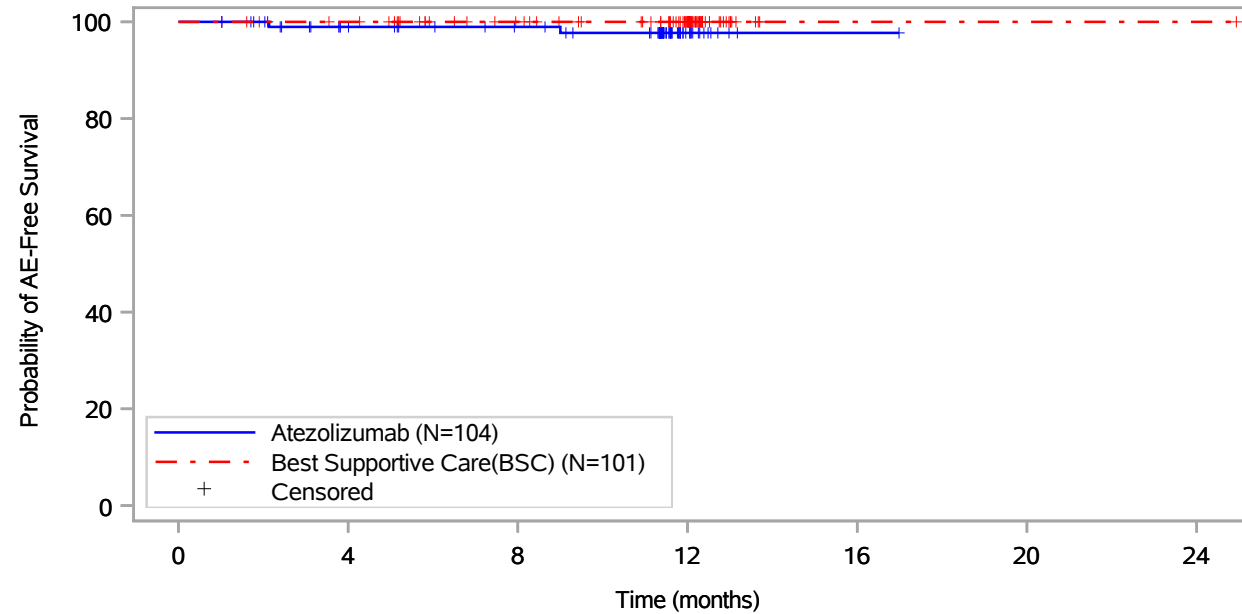
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Erythema



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

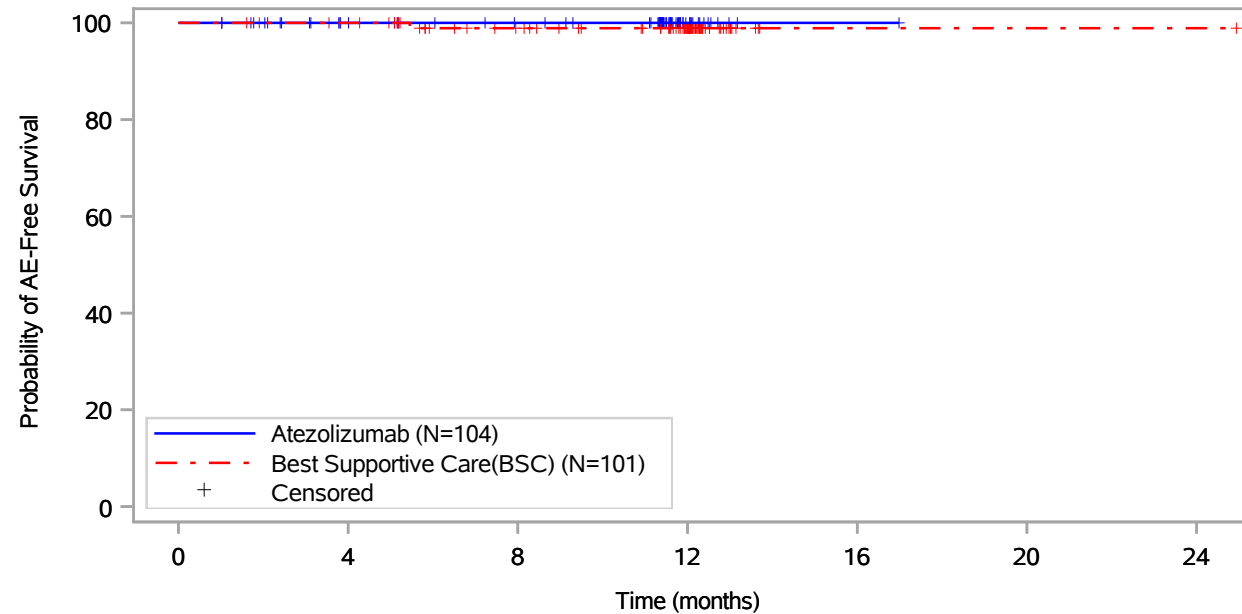
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Miliaria



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

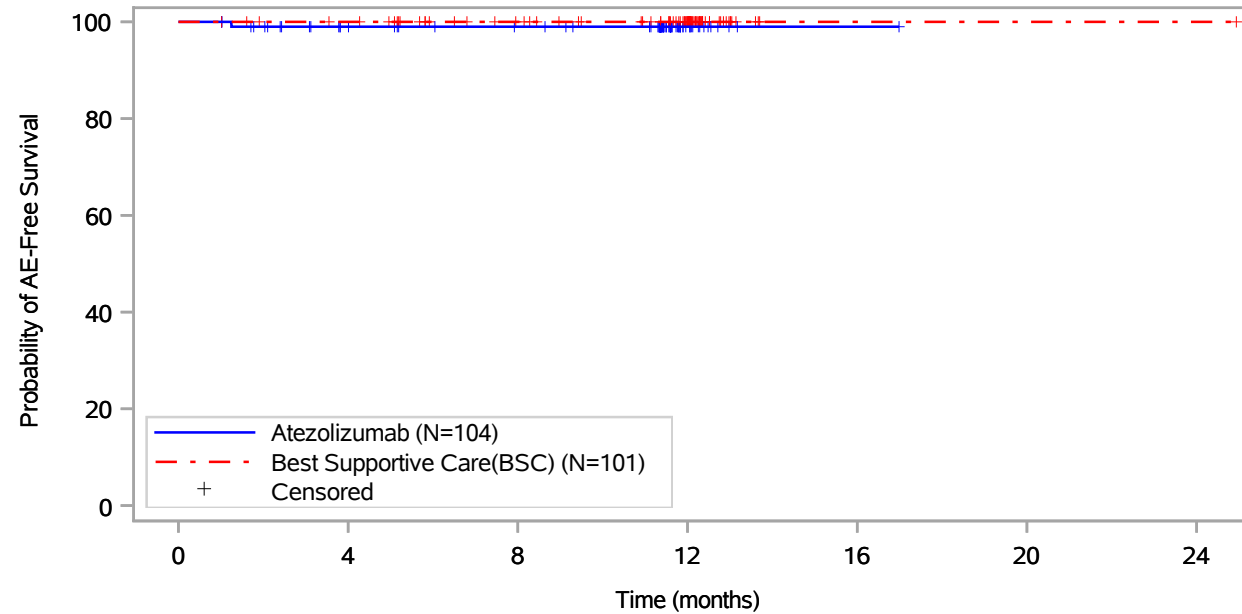
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Onychoclasia



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

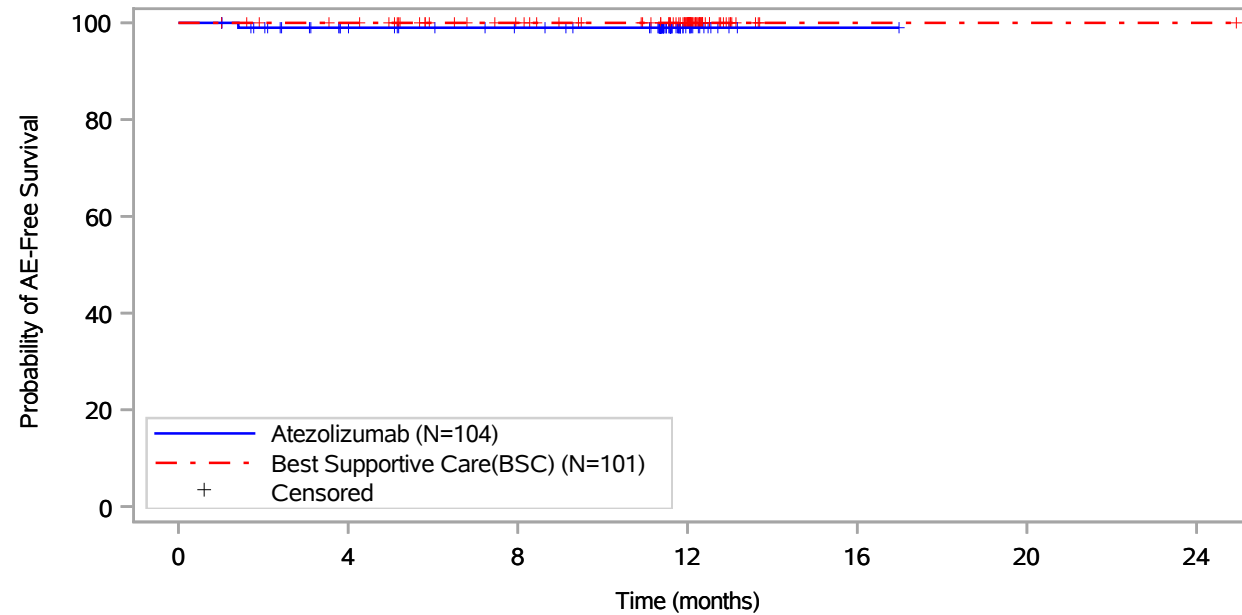
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Papule



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

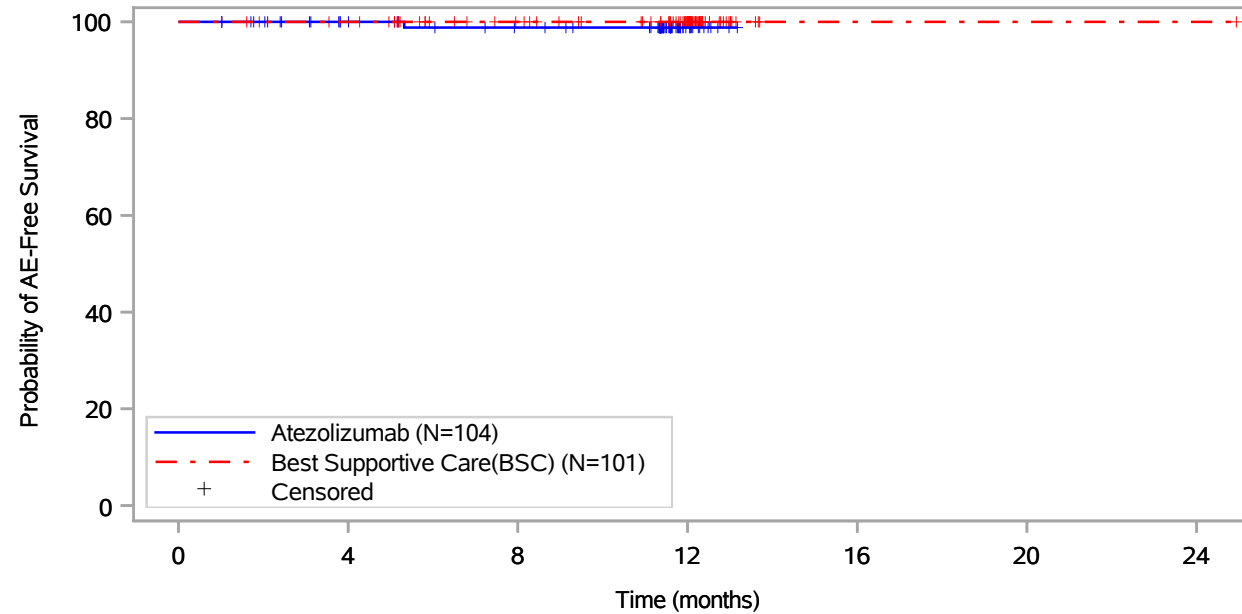
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

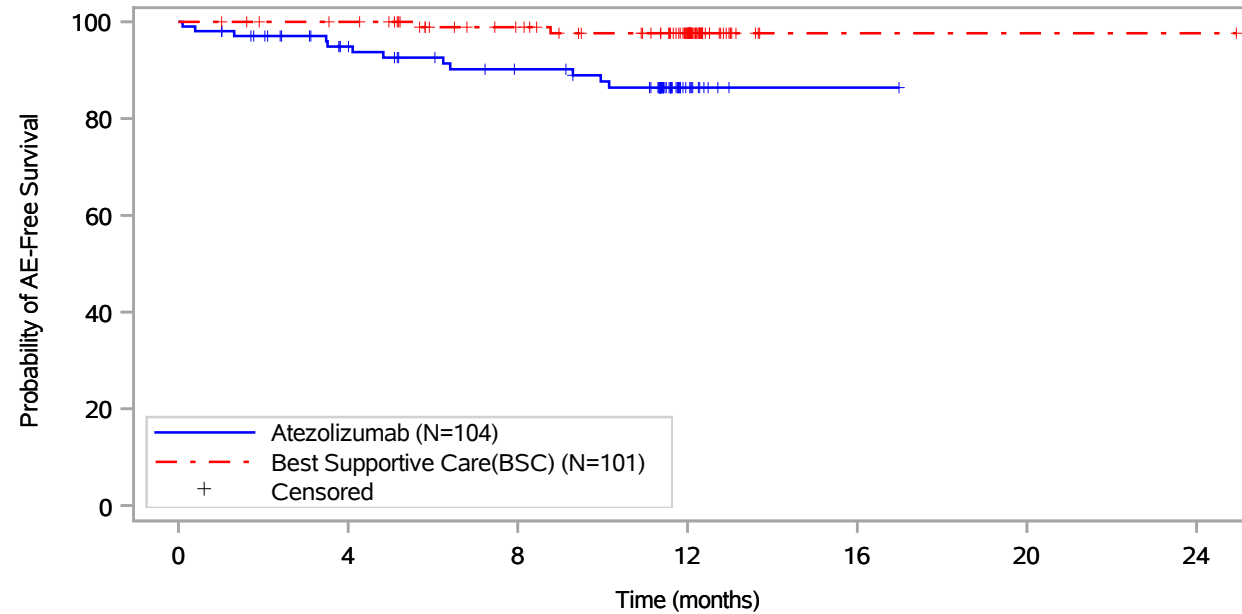
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Pruritus



Patients at risk							
Atezolizumab (N=104)	104	84	73	11	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	81	91	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

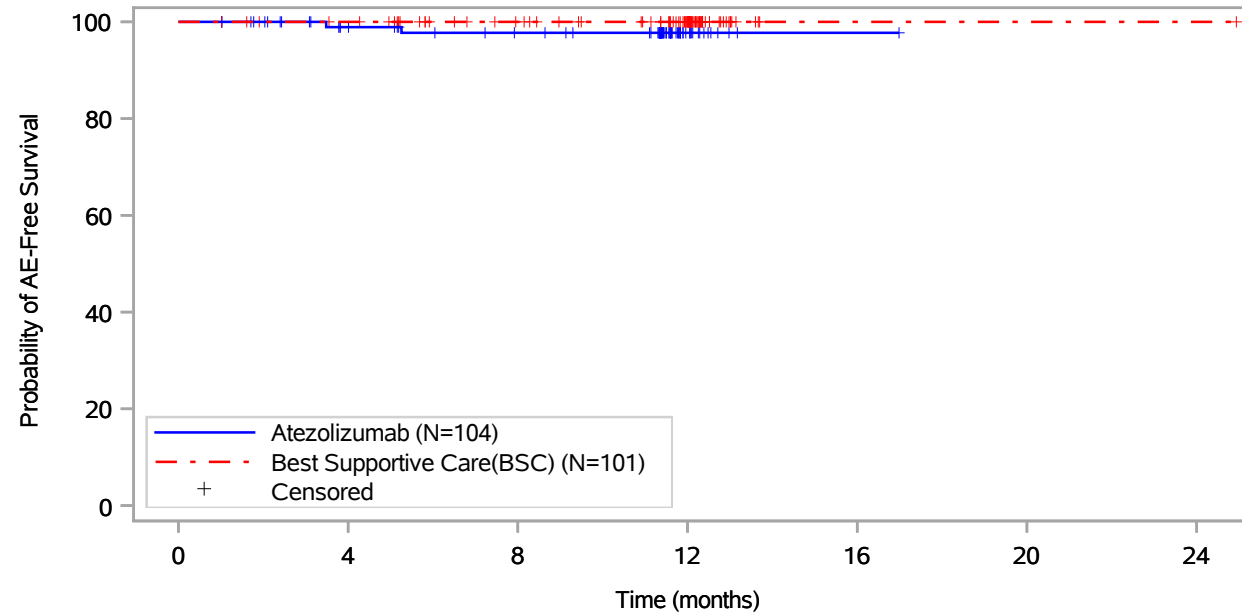
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Psoriasis



Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

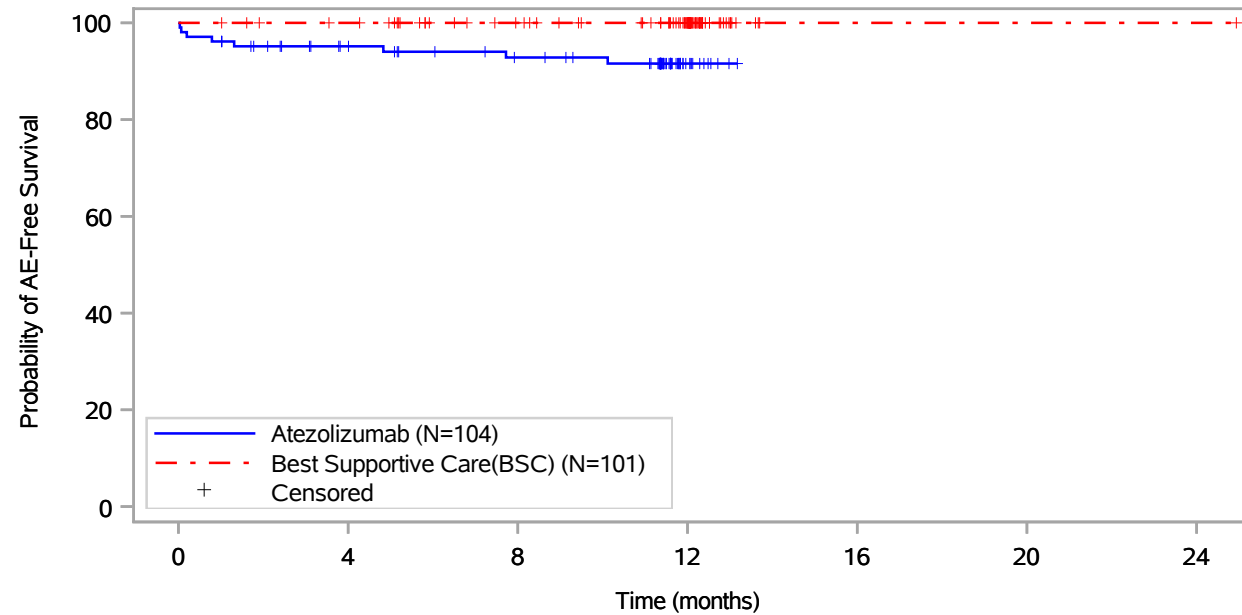
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	86	77	11	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	13	20	85	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

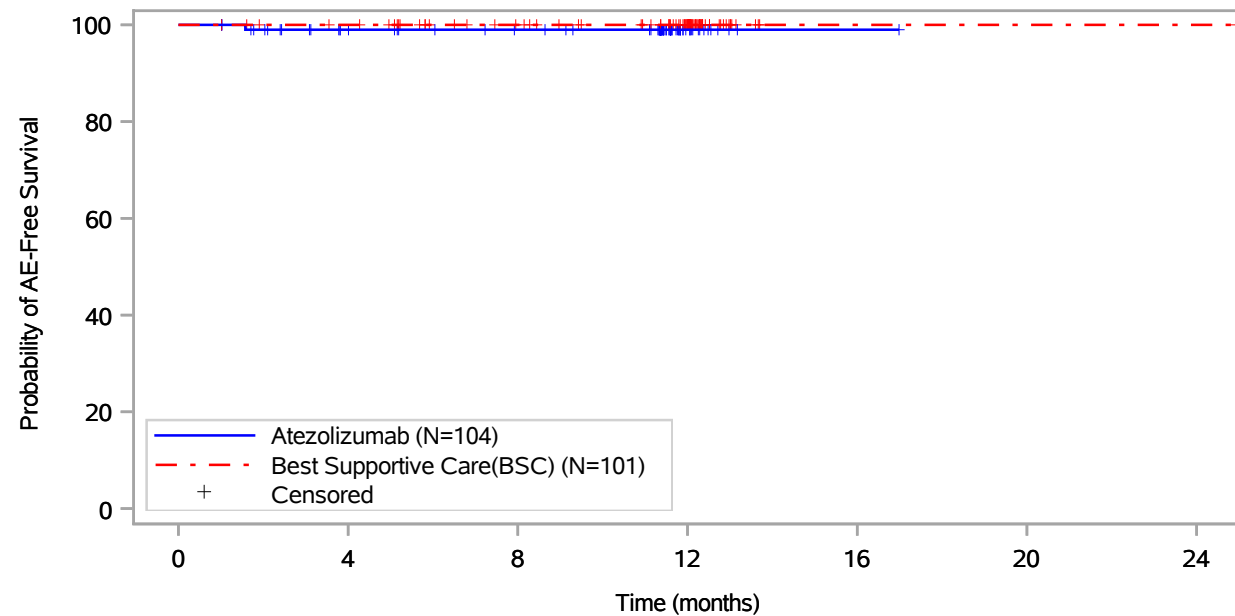
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash erythematous



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

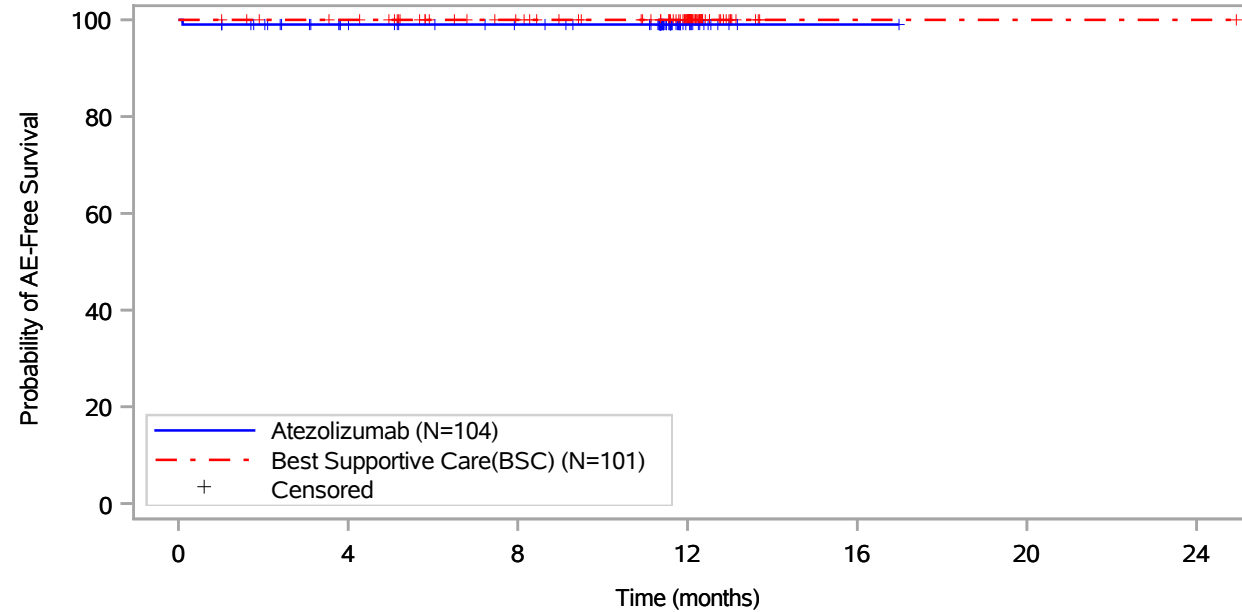
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash maculo-papular



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

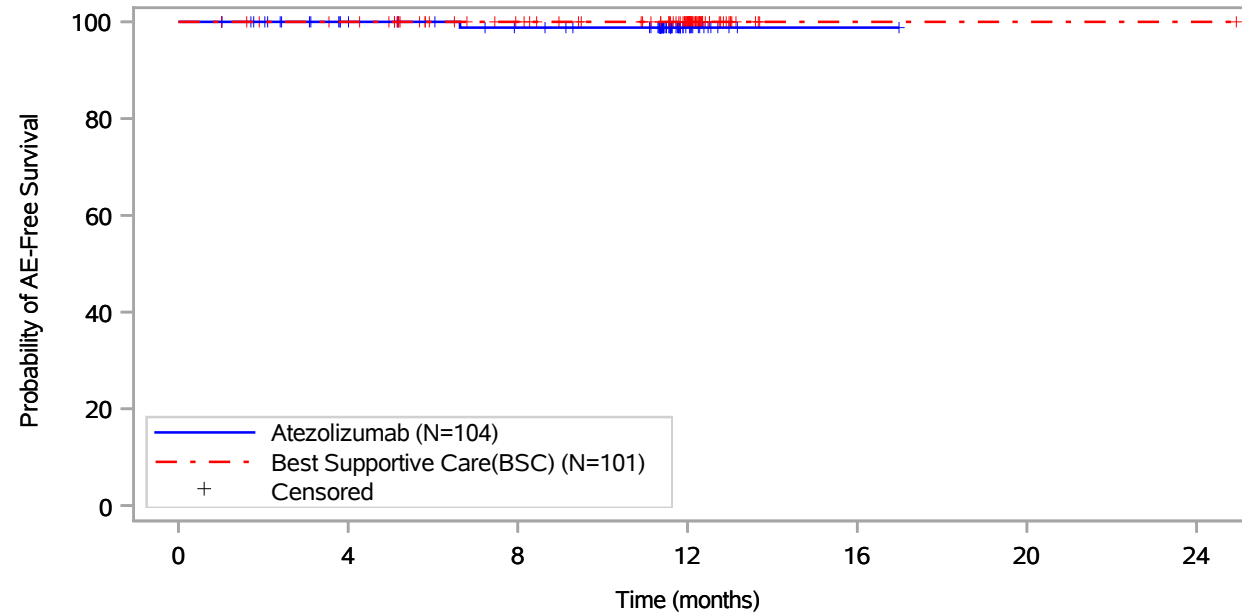
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash pruritic



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

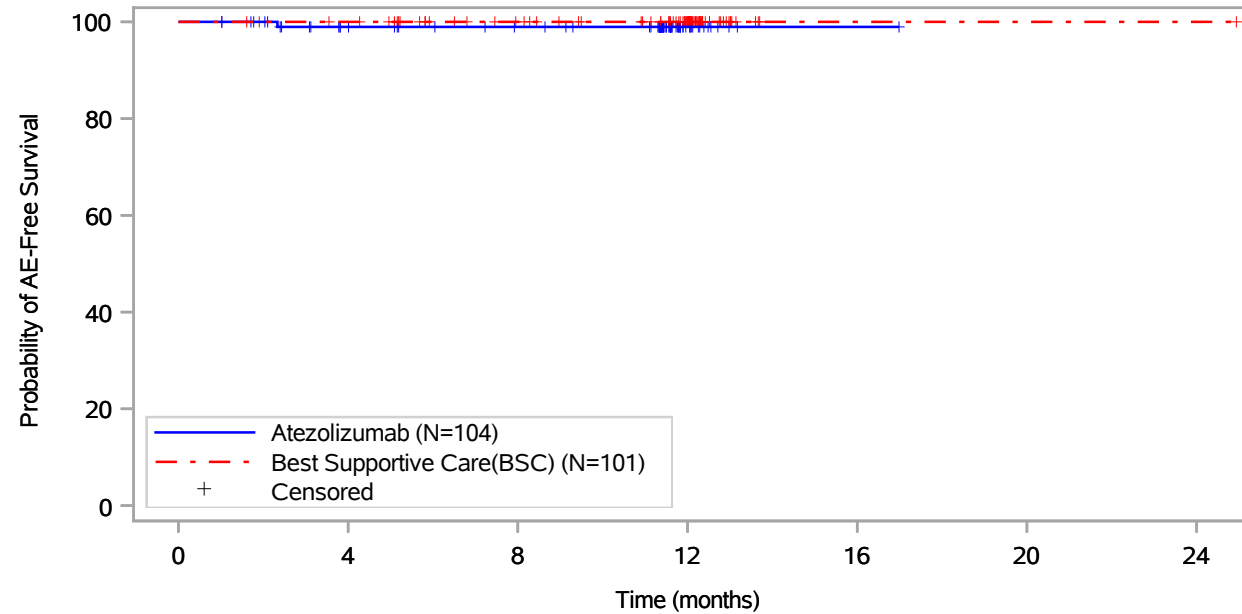
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Scar pain



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

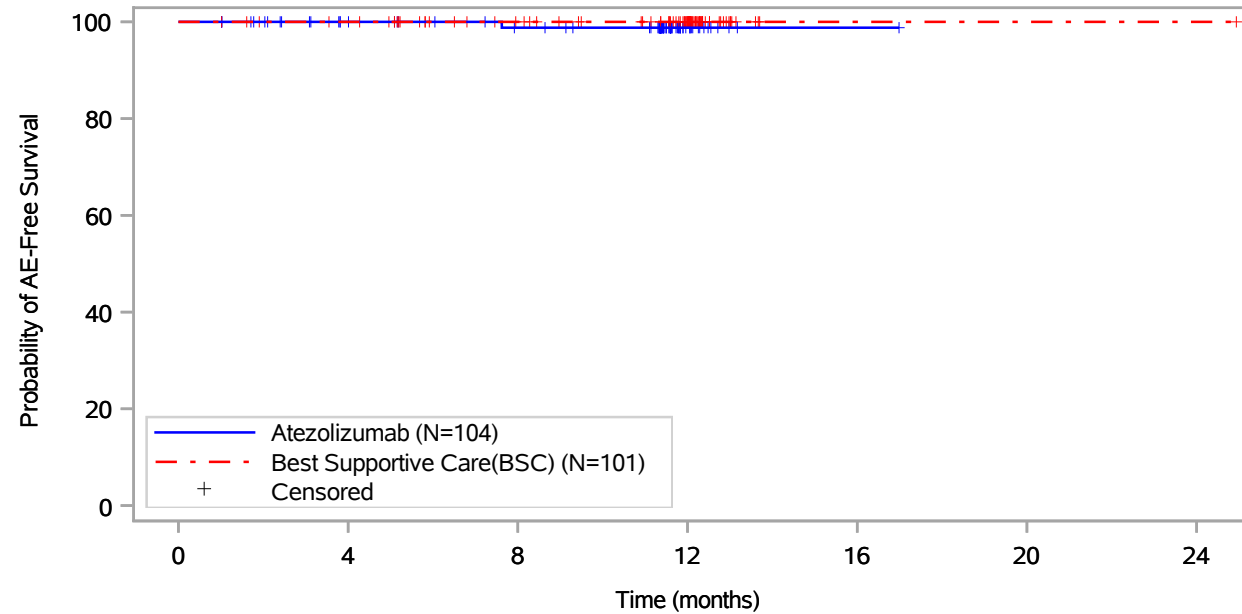
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Skin burning sensation



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

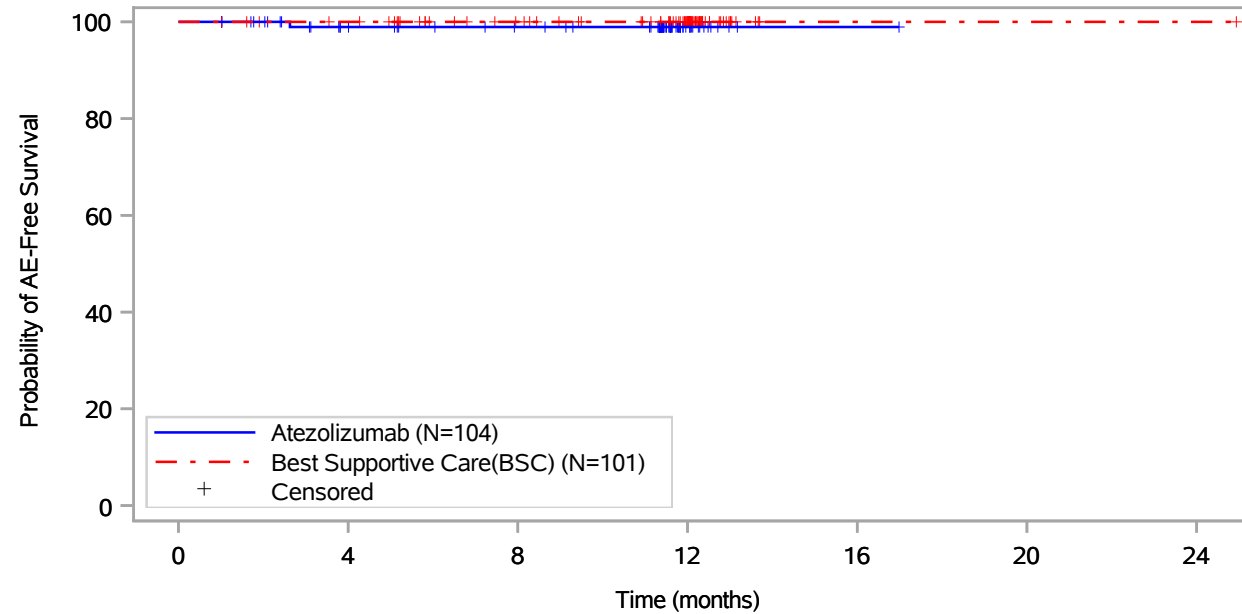
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Skin exfoliation



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

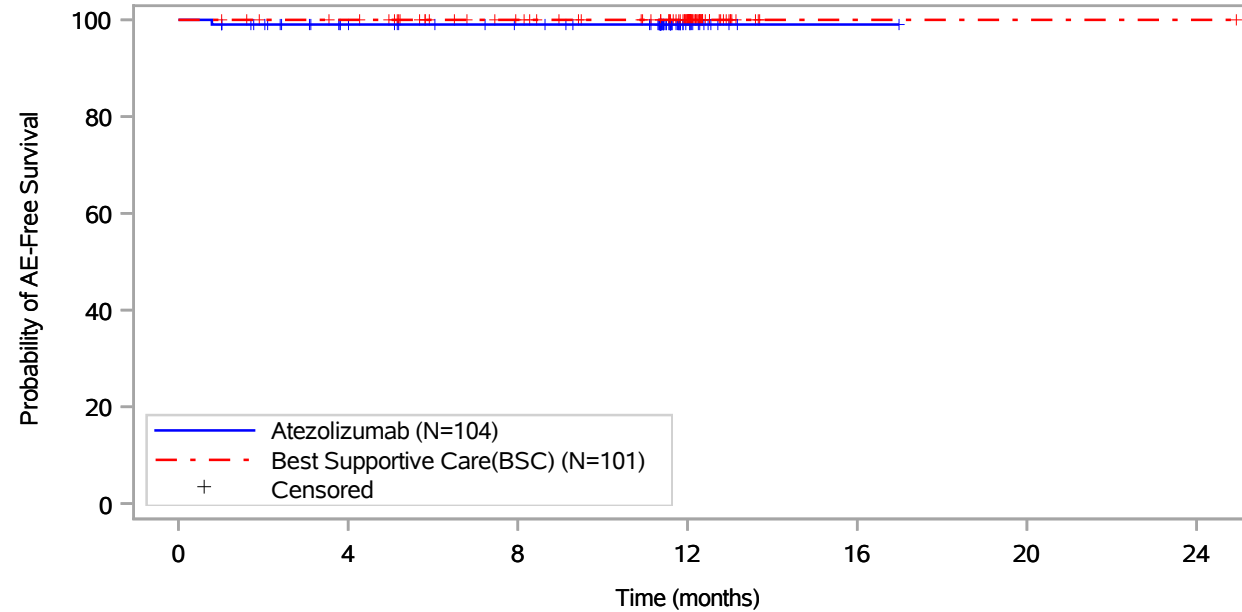
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Toxic skin eruption



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

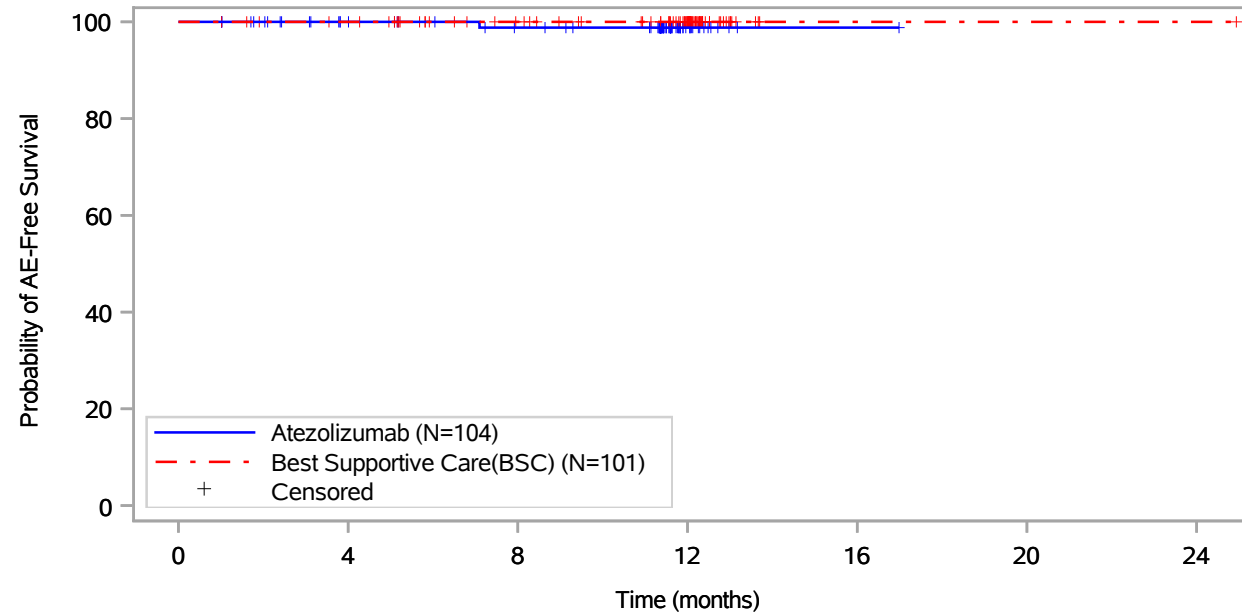
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Urticaria



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

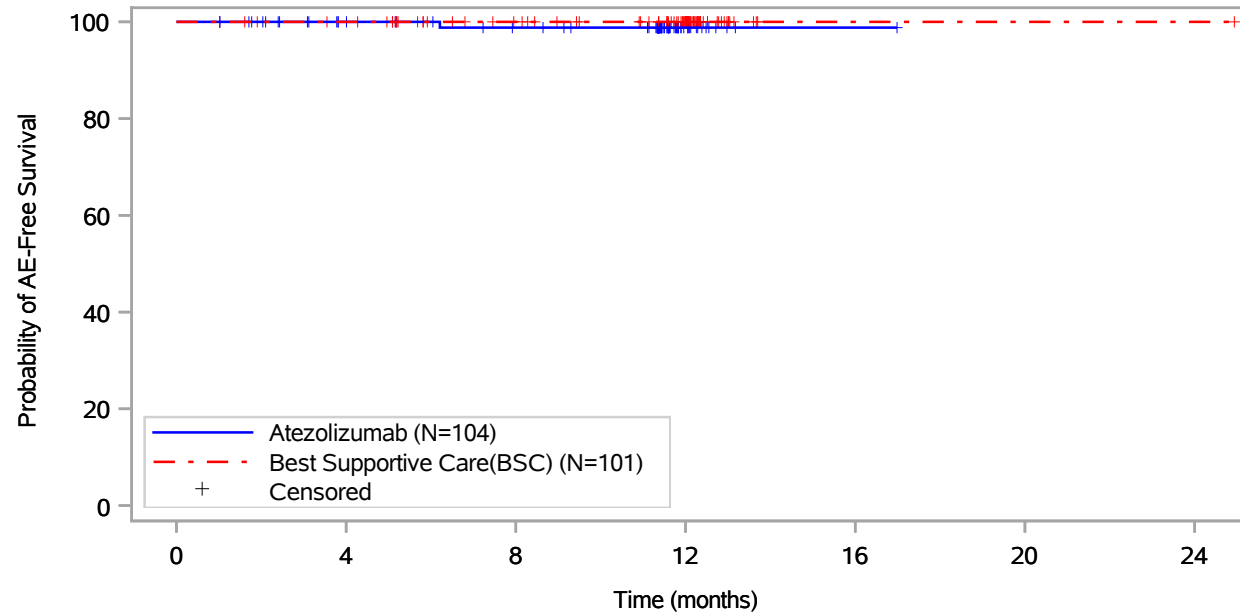
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Vitiligo



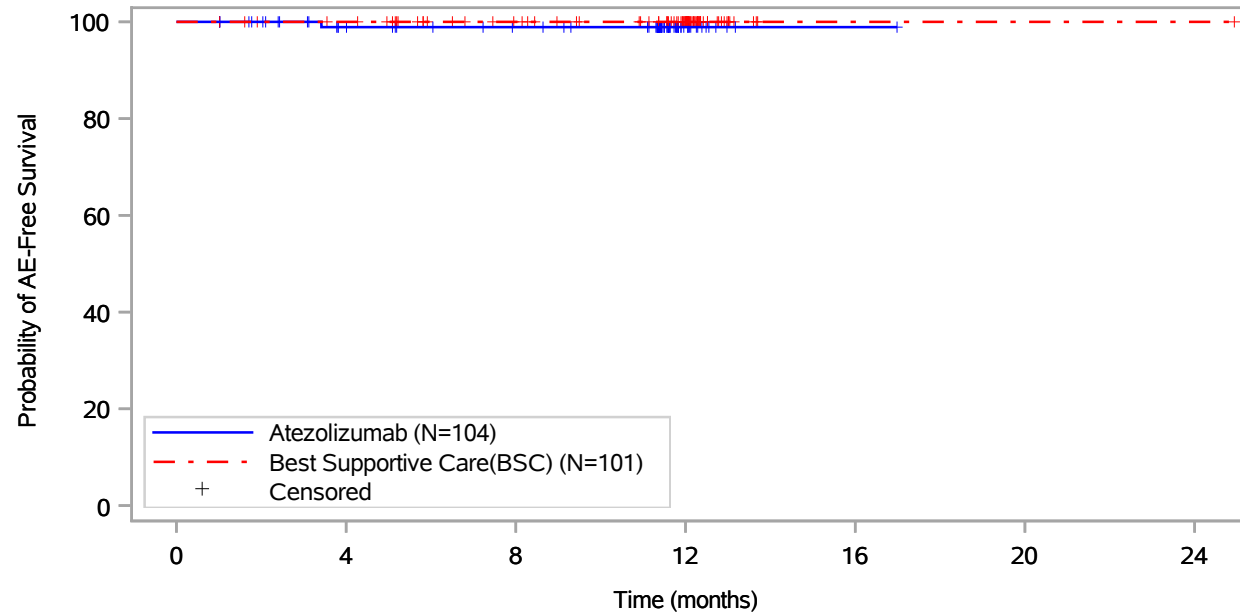
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Surgical and medical procedures, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

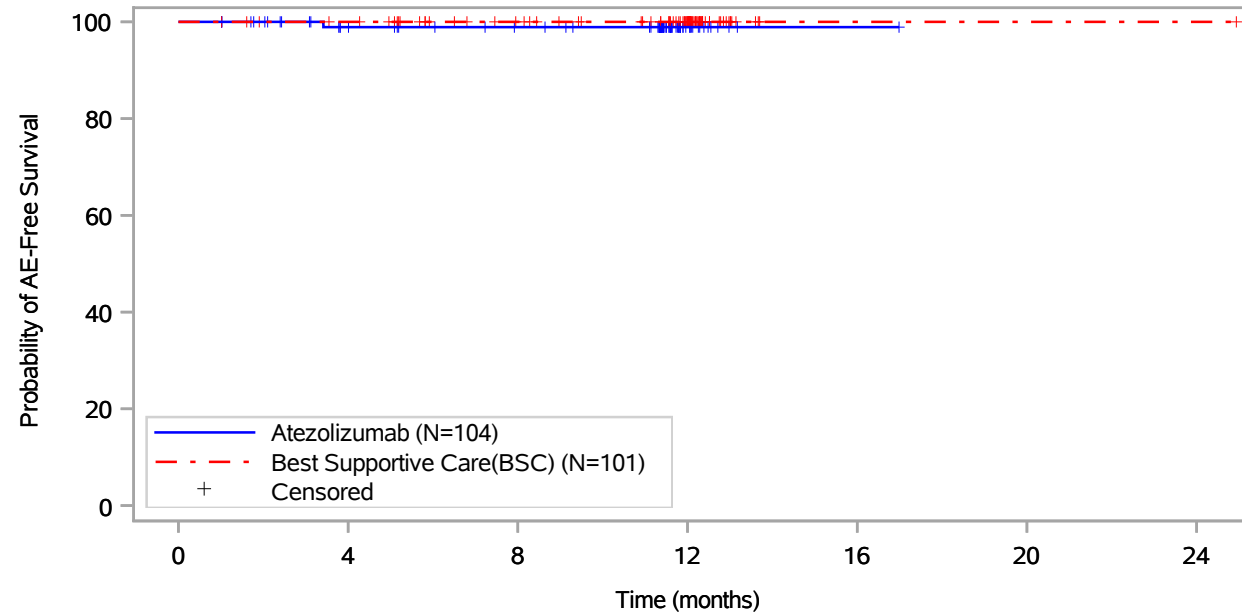
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Surgical and medical procedures, Cancer surgery



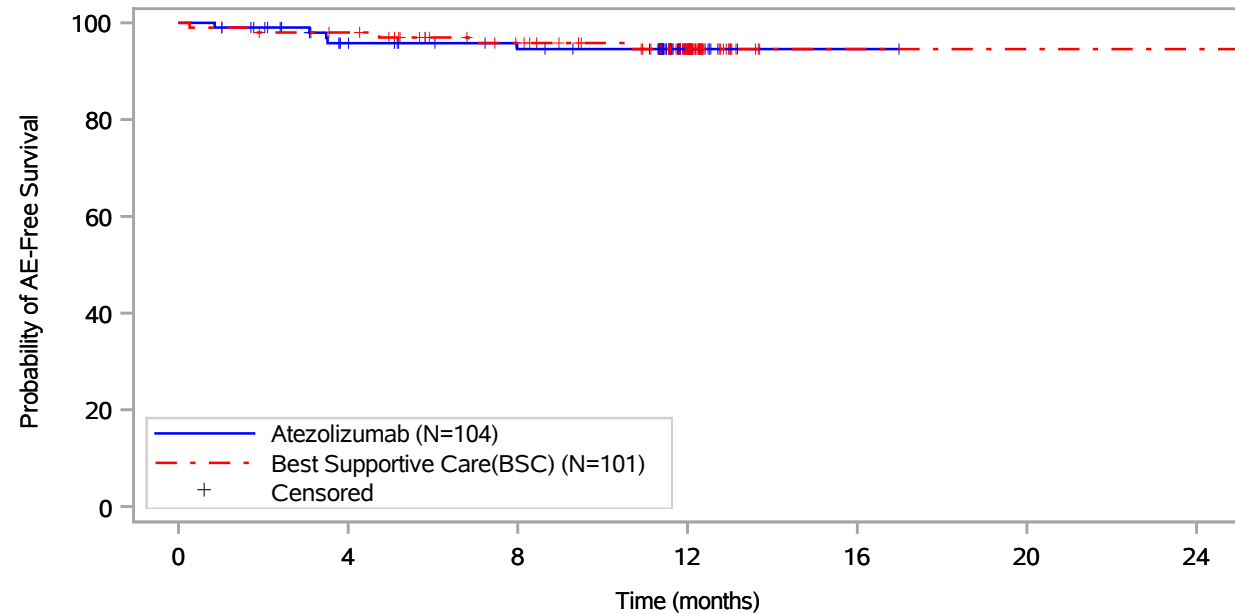
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, All



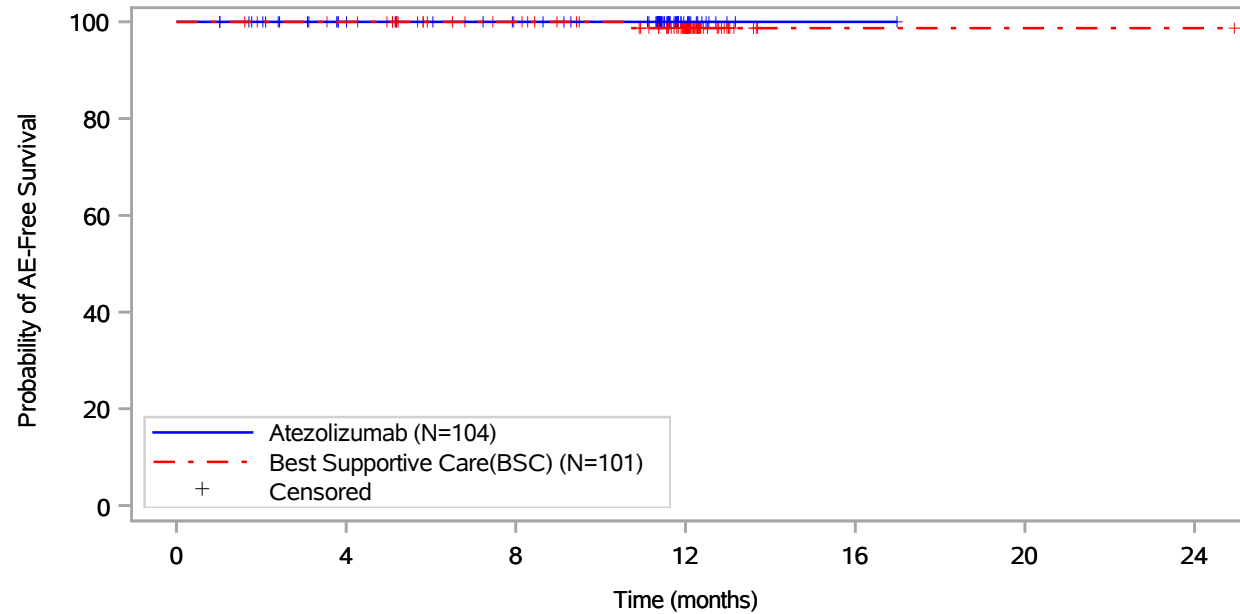
Patients at risk							
Atezolizumab (N=104)	104	85	78	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	85	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	43	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Hot flush



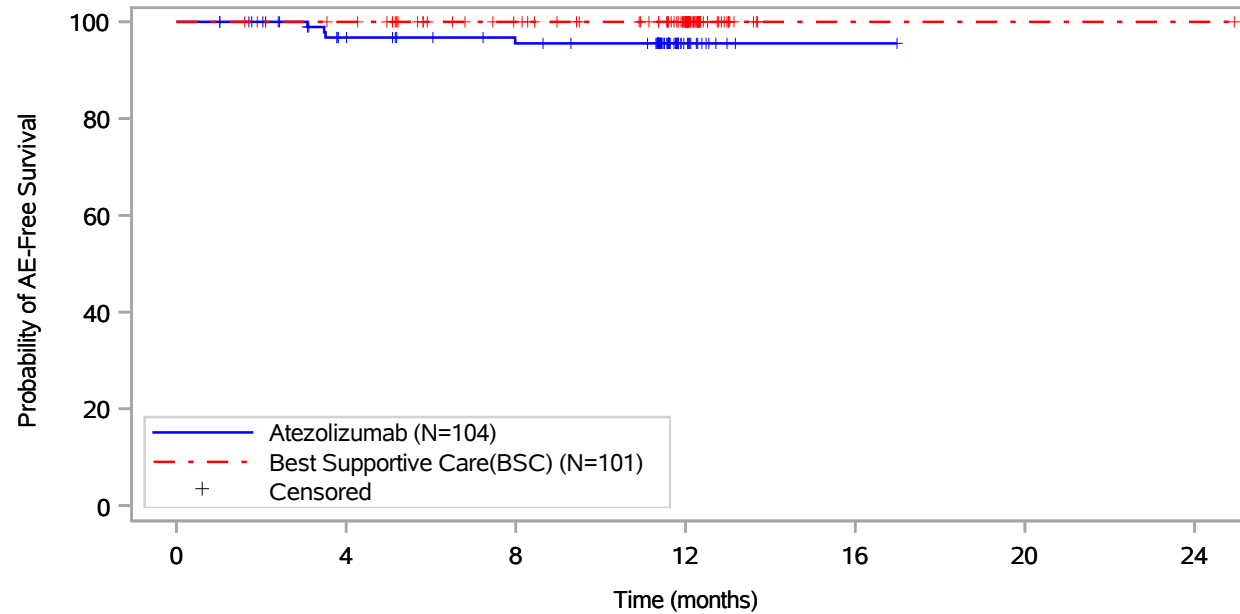
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Hypertension



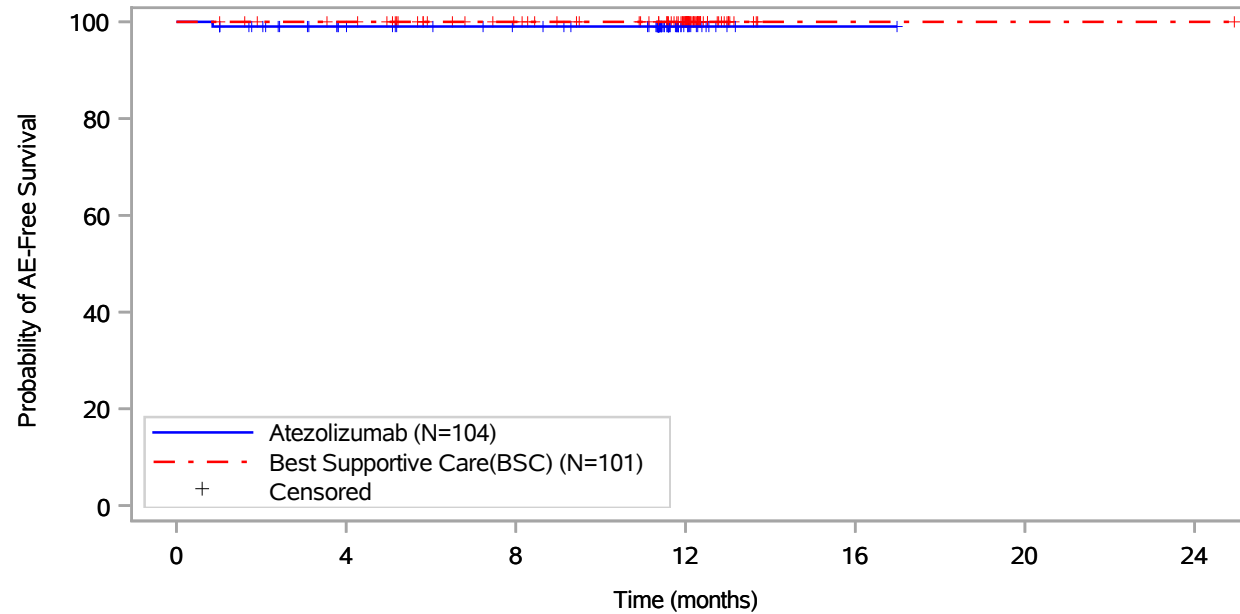
Patients at risk							
Atezolizumab (N=104)	104	86	79	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	86	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Hypotension



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

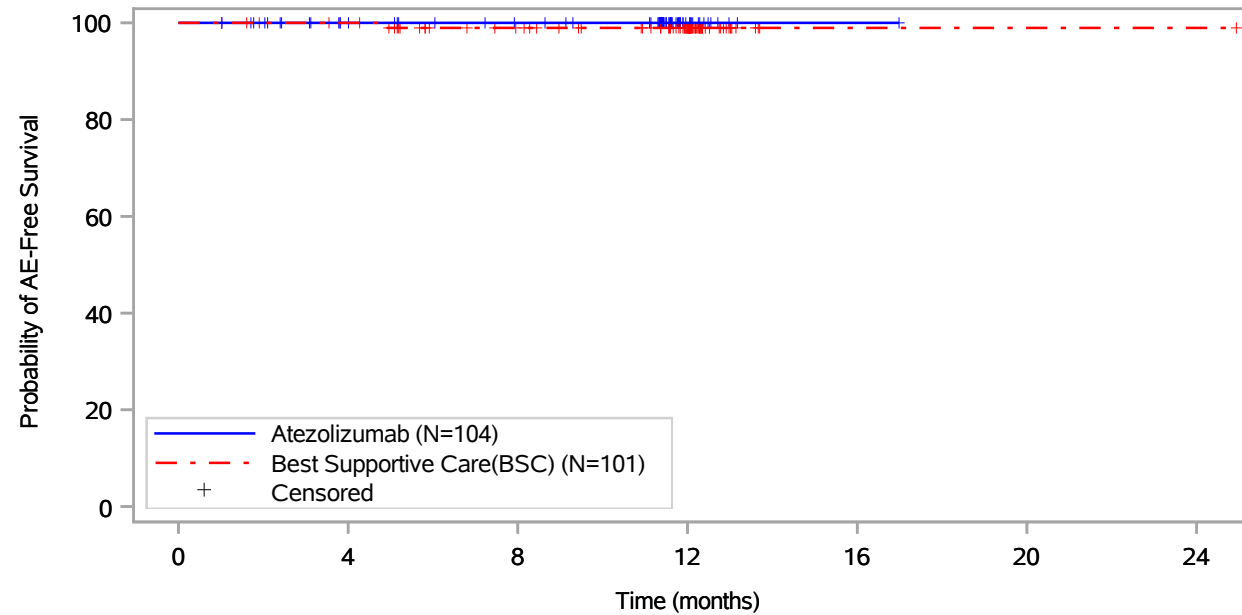
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Vascular disorders, Orthostatic hypotension



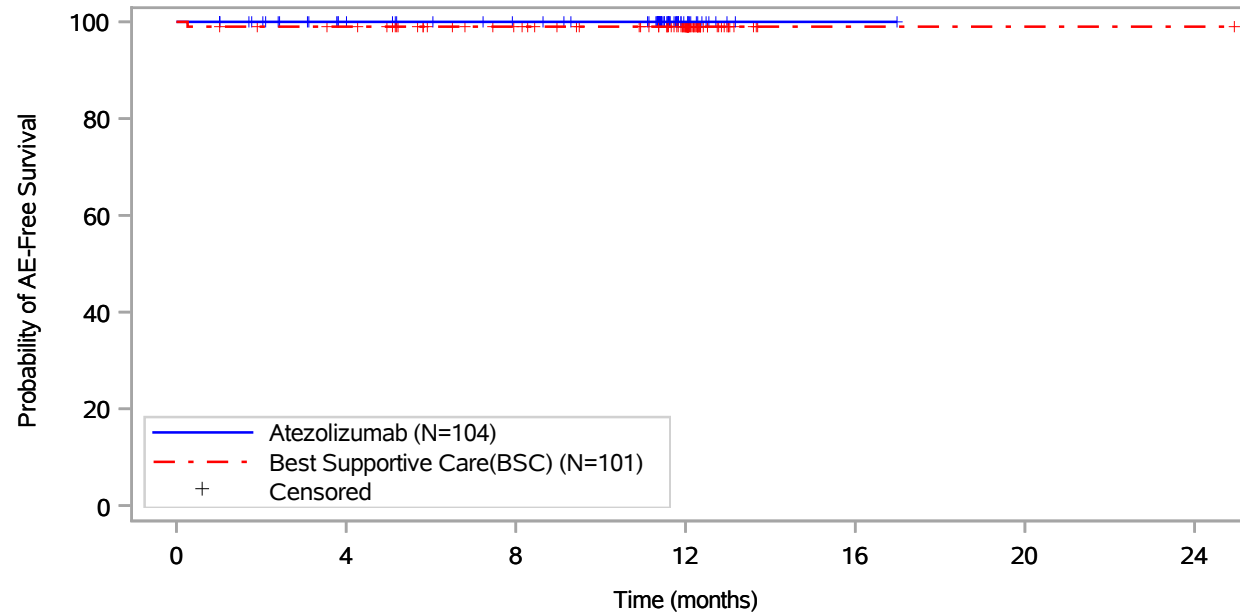
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Phlebitis



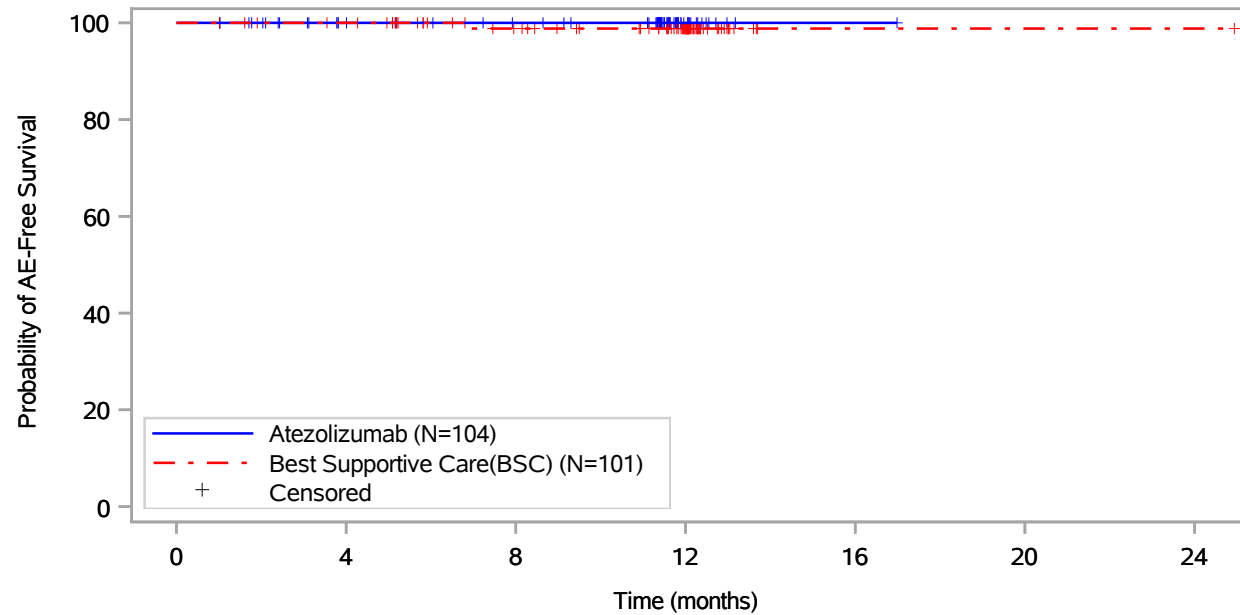
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	17	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Phlebitis superficial



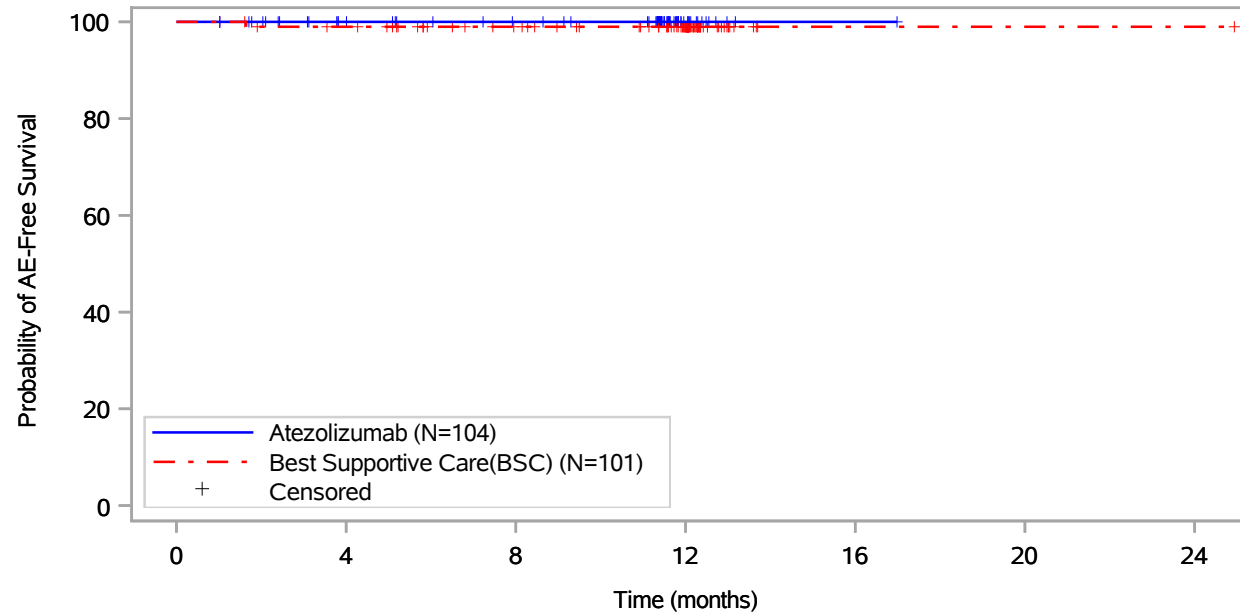
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
 Vascular disorders, Vascular stenosis



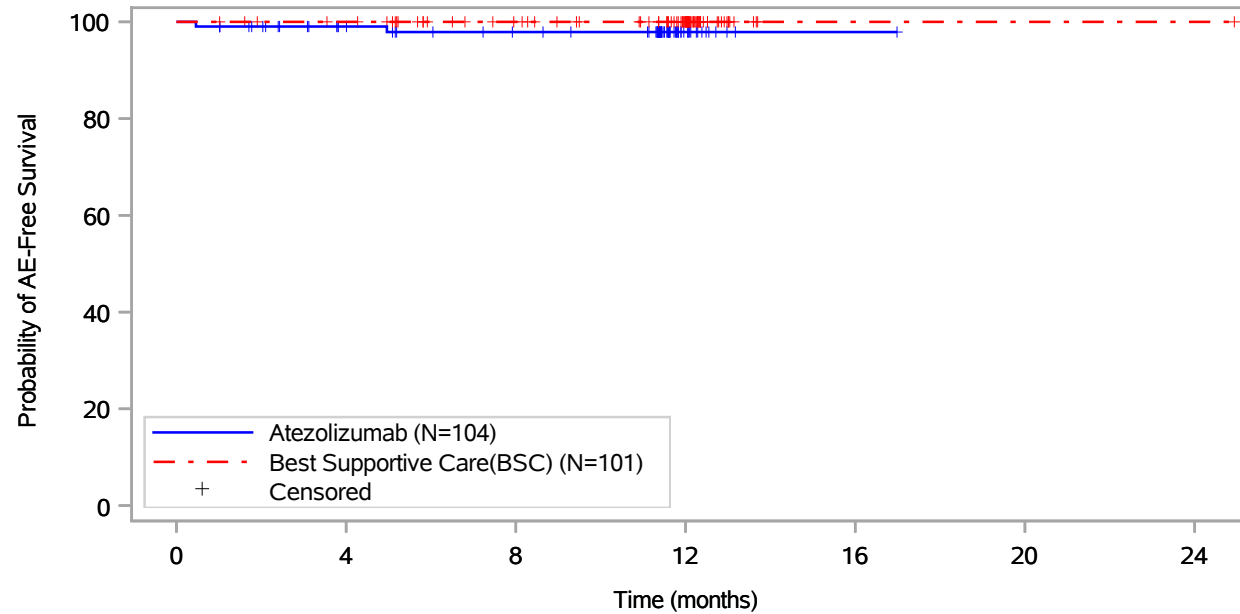
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..ACE_OS_IA/prod/output/g_km_soc_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Blood and lymphatic system disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

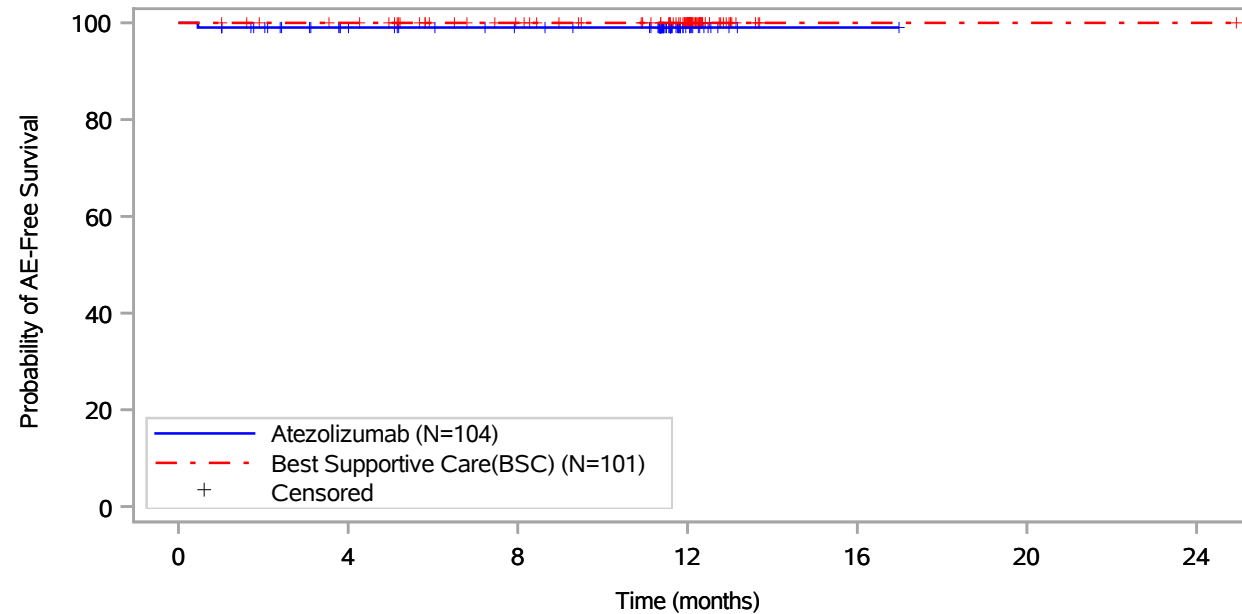
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

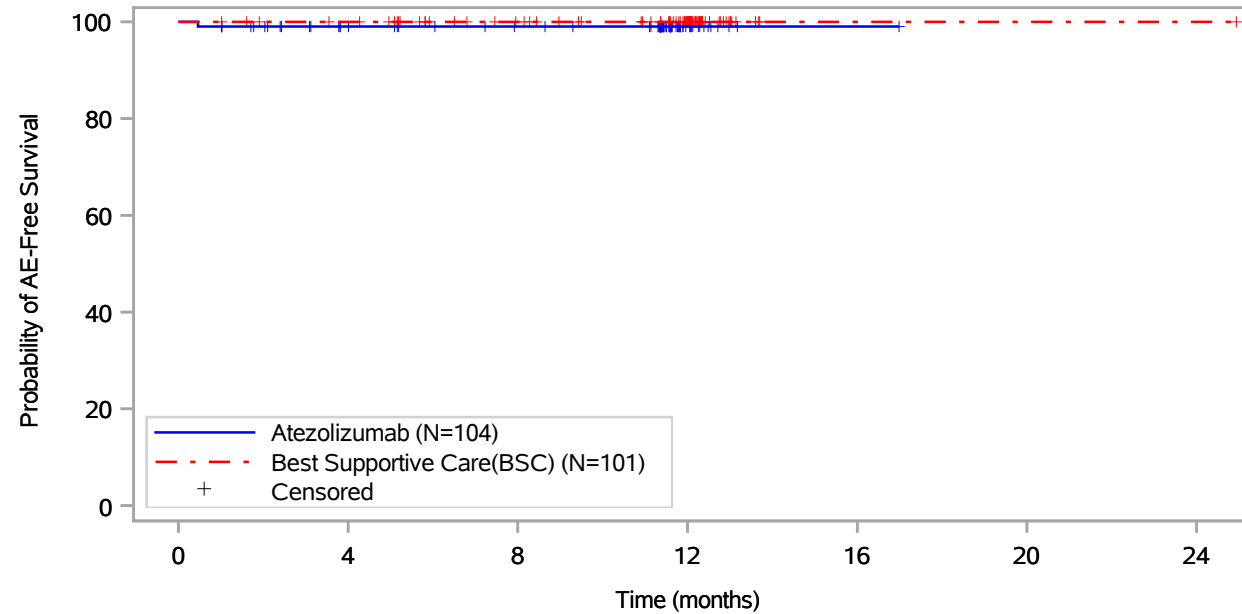
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

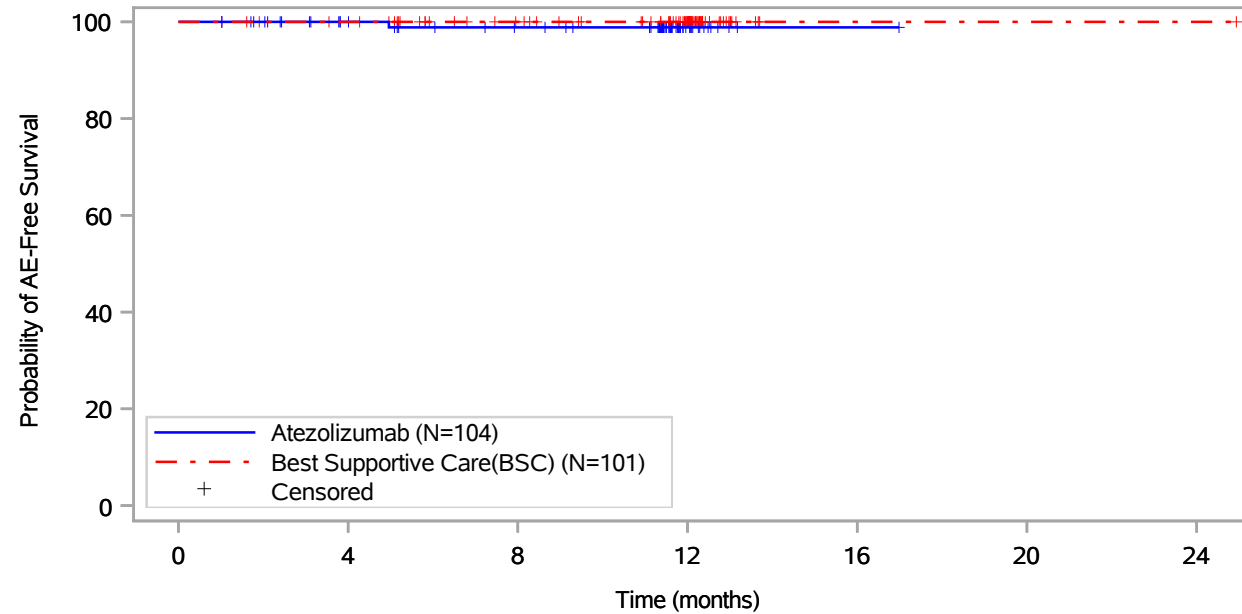
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



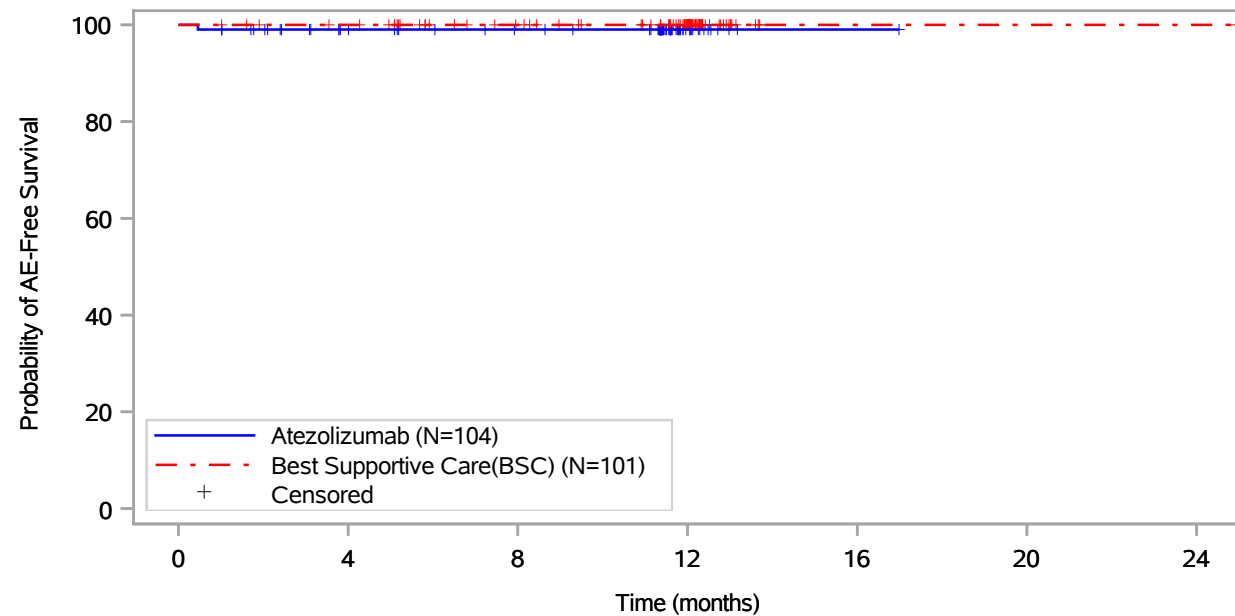
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Endocrine disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

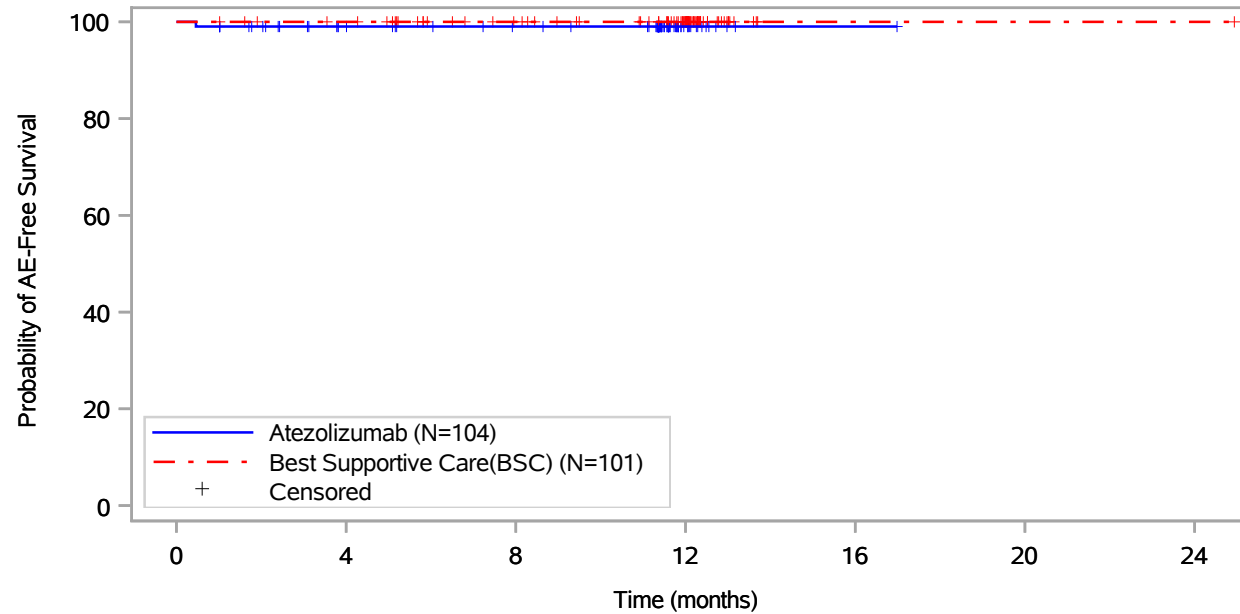
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..OS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



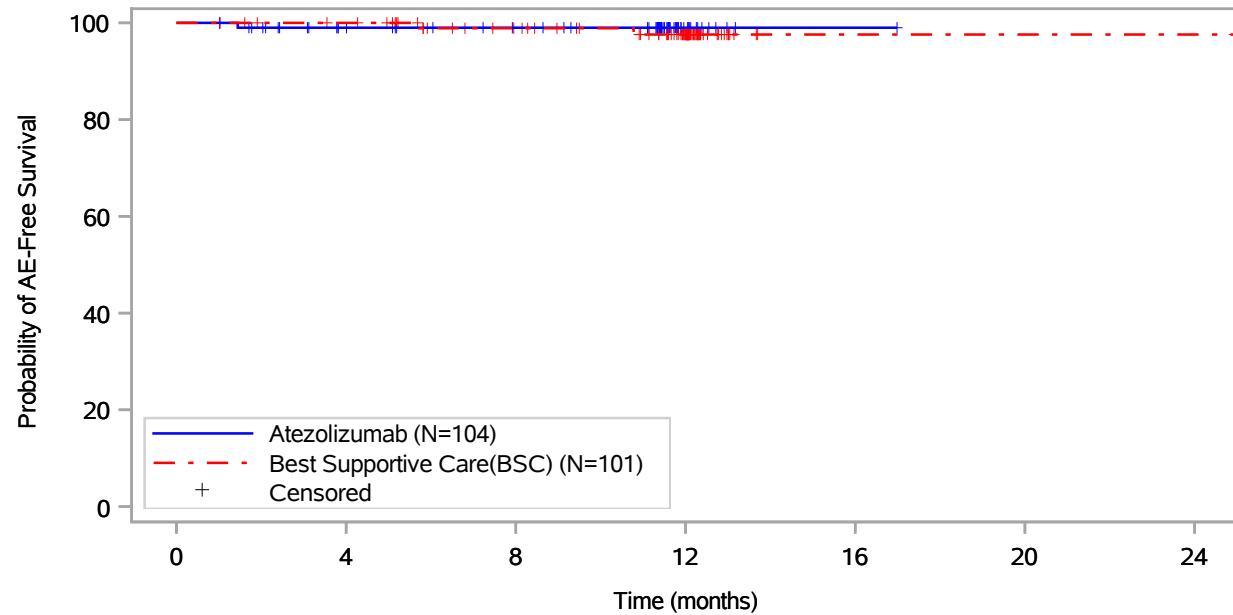
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..OS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Eye disorders, All



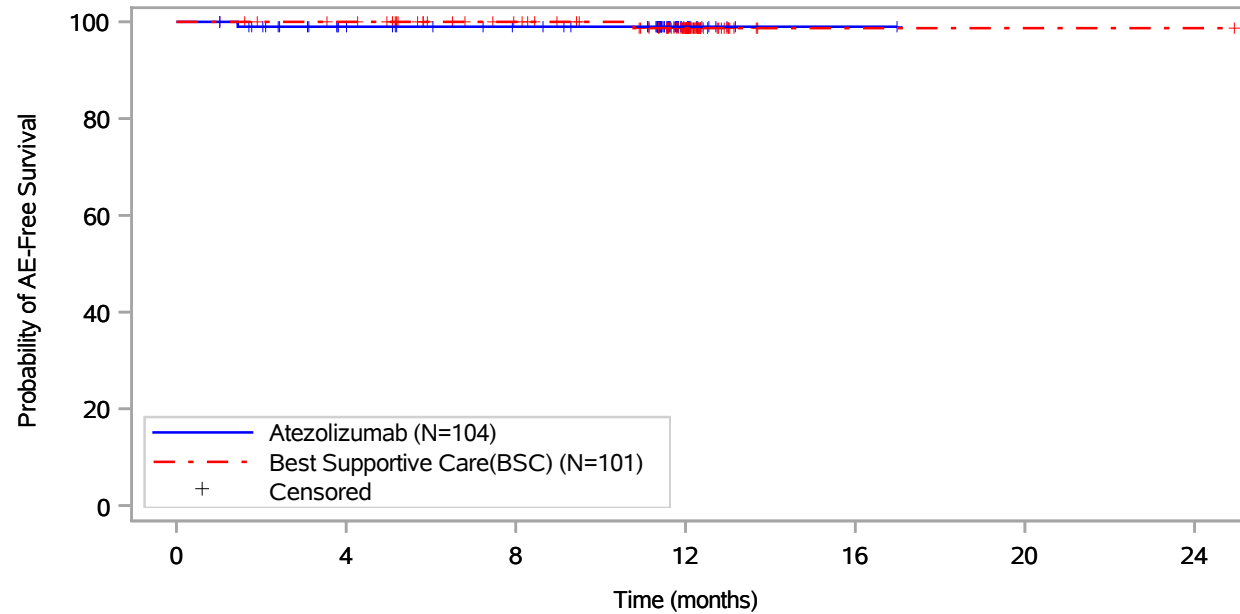
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..OS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Eye disorders, Cataract



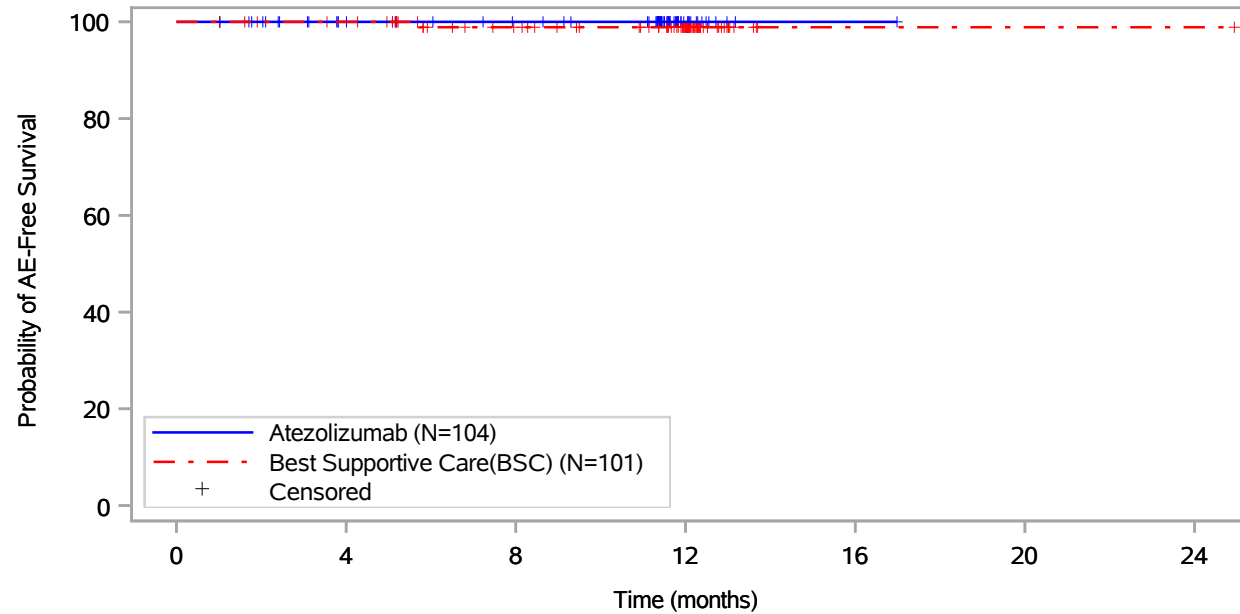
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..OS_IA/prod/output/g_km_soc_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Eye disorders, Vitreous haemorrhage



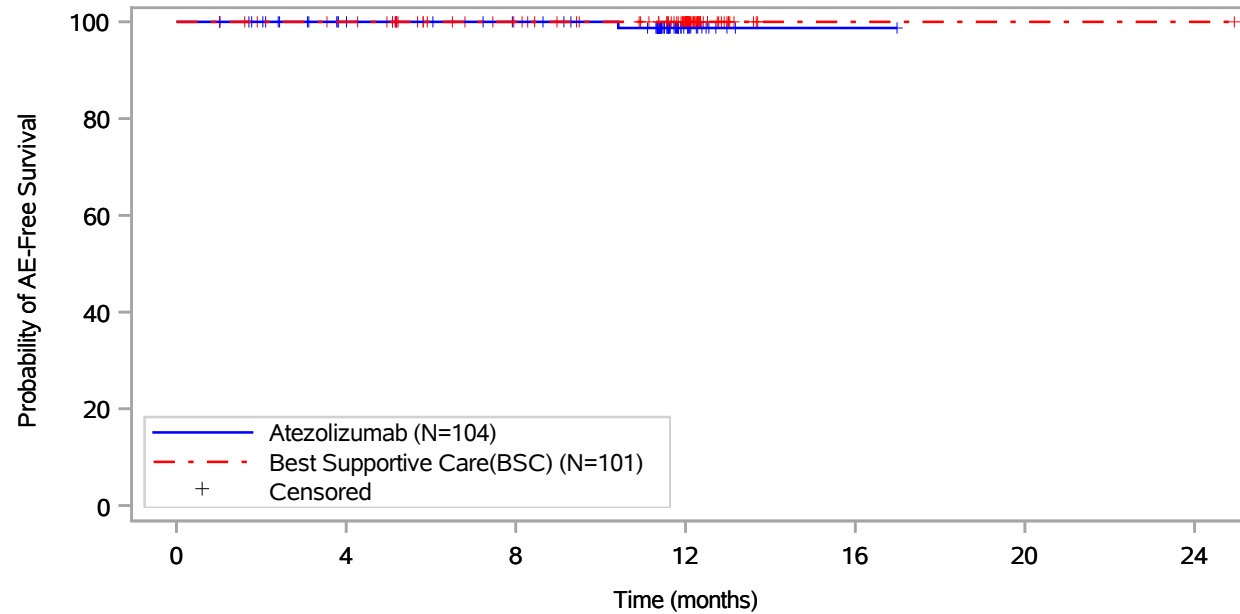
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, All



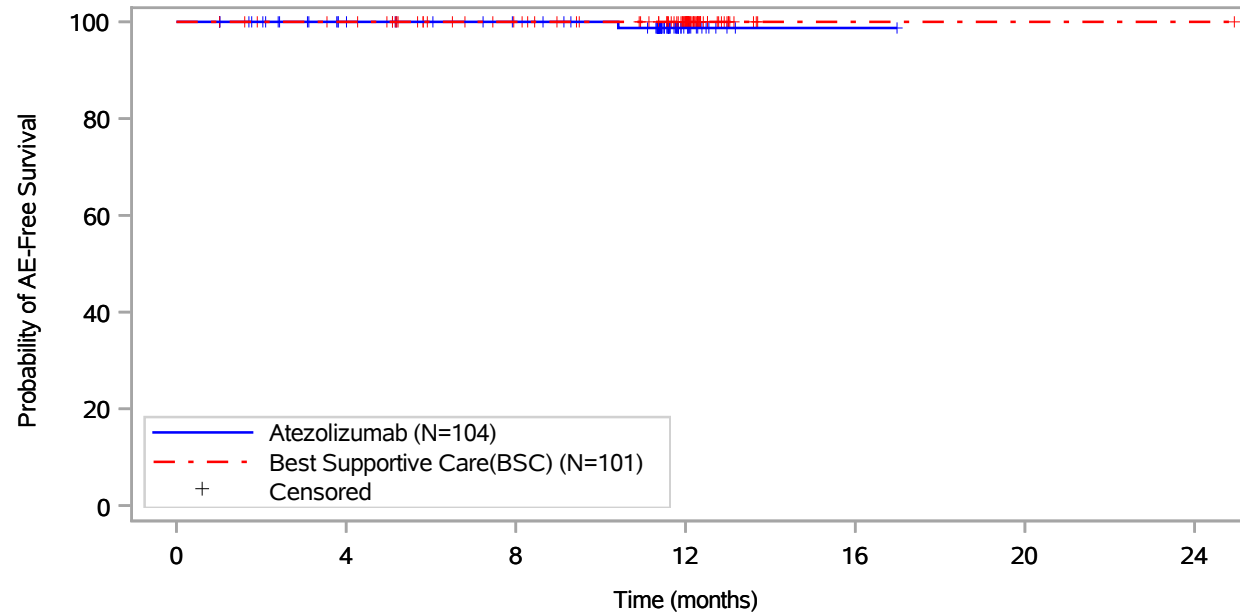
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Colitis



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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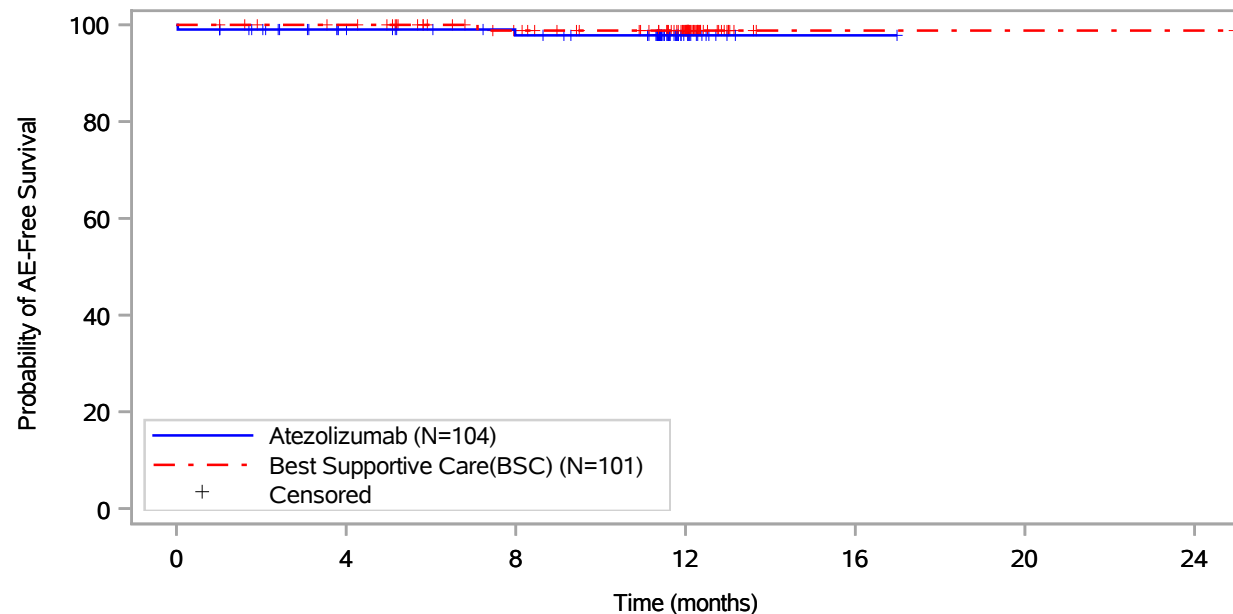
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 3-5 Adverse Event

STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

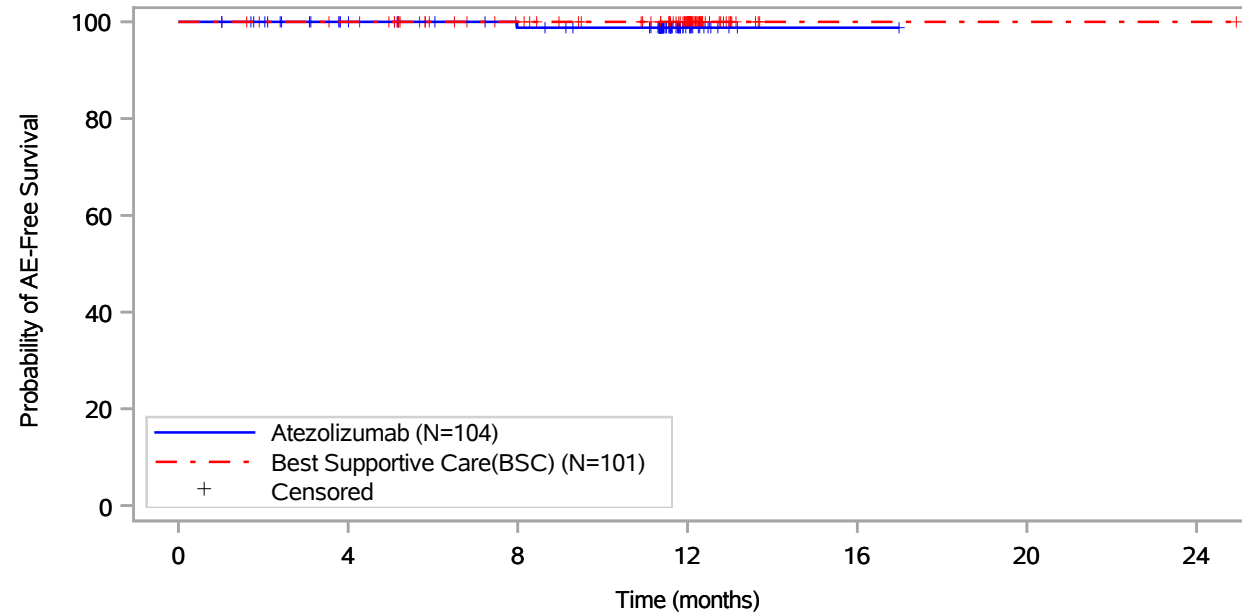
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

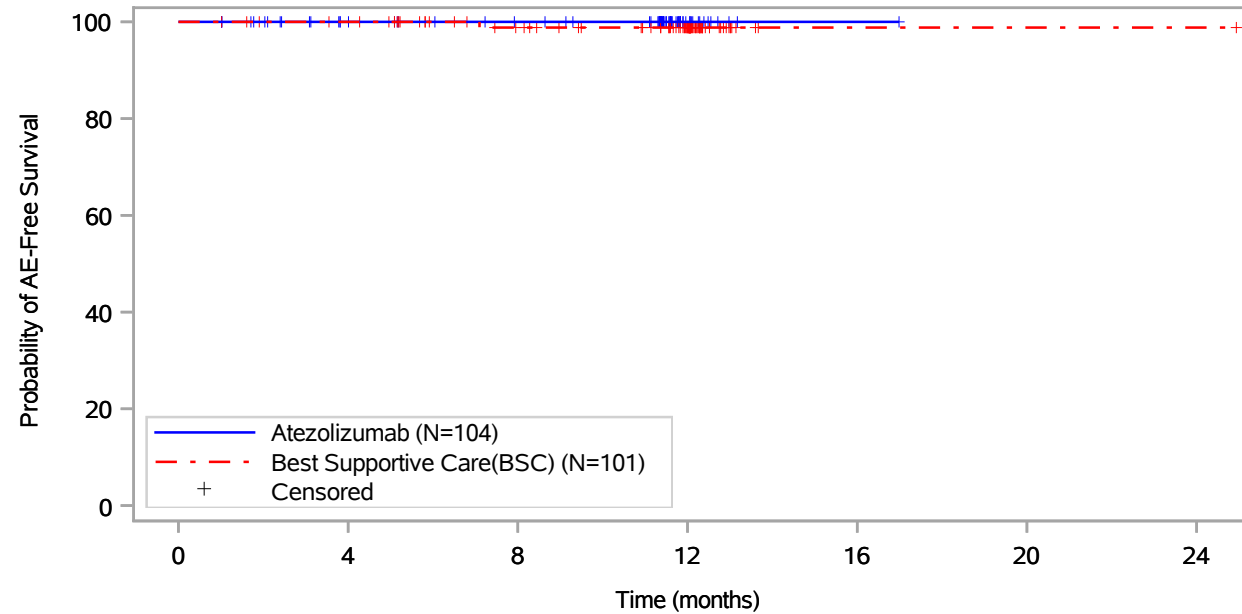
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

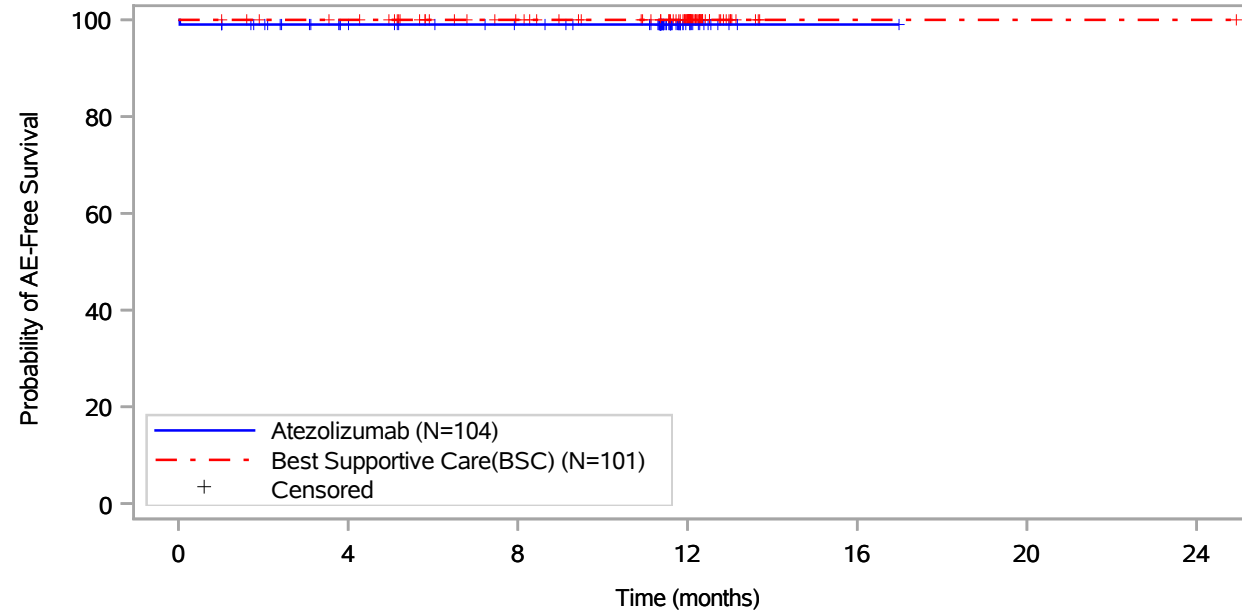
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pyrexia



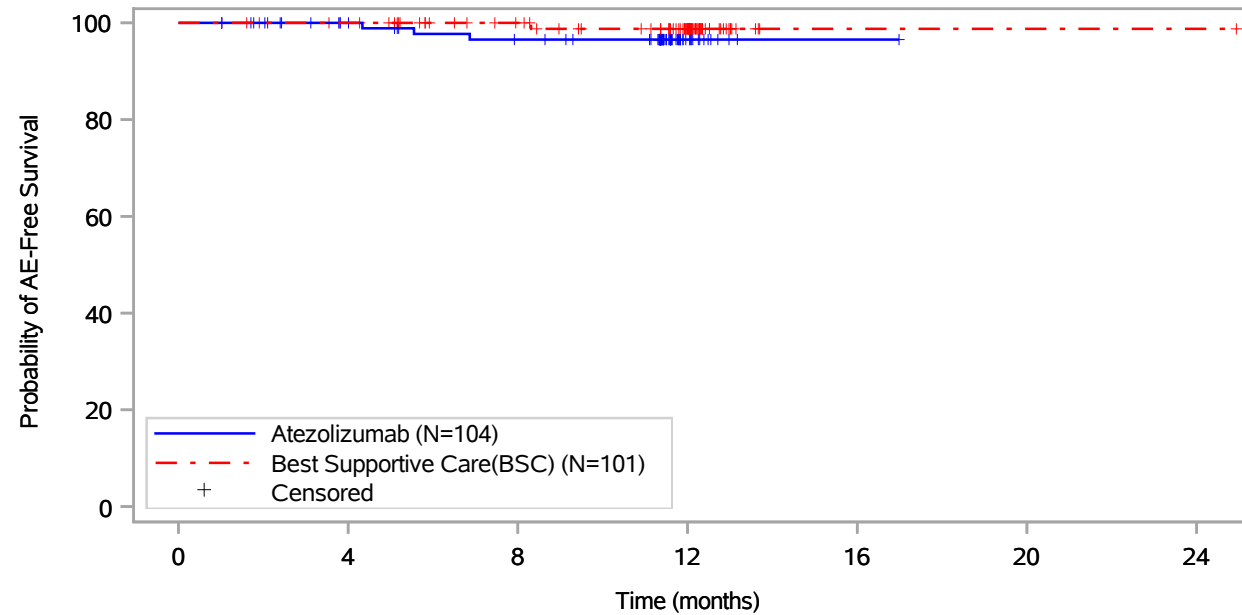
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, All



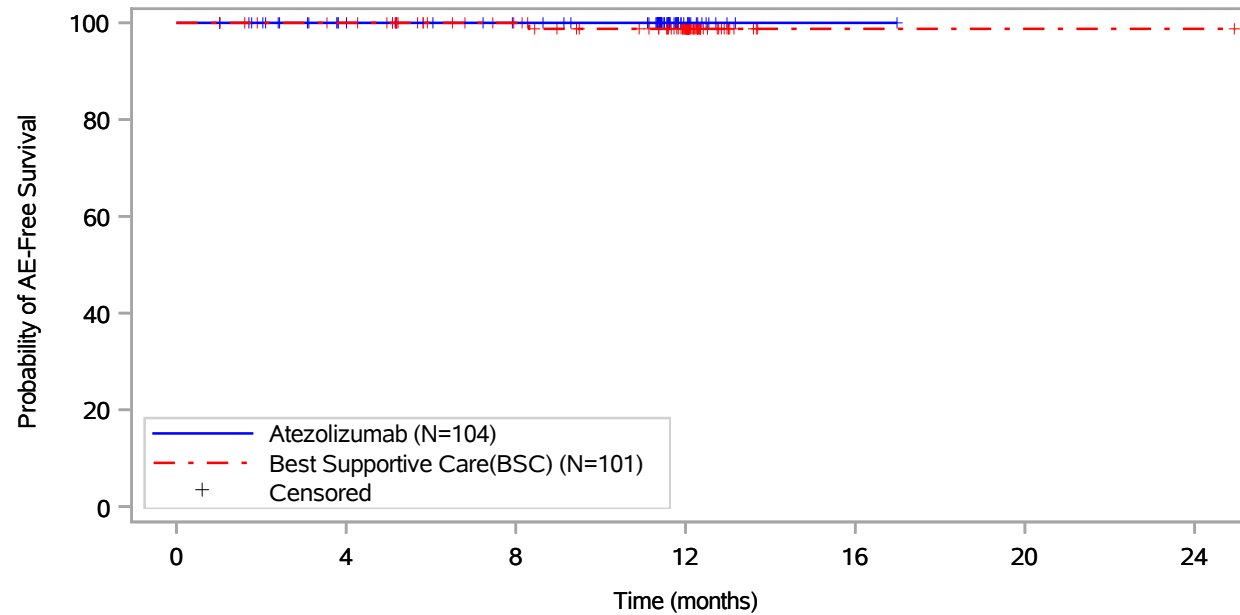
Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Cholestasis



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

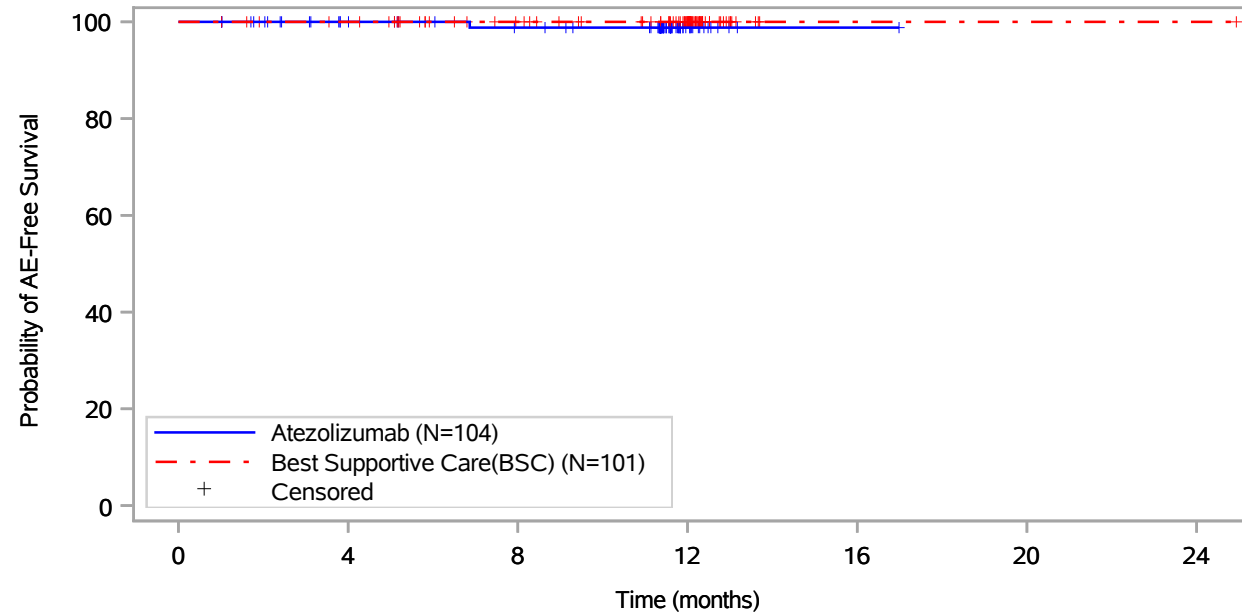
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Hepatobiliary disorders, Drug-induced liver injury



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

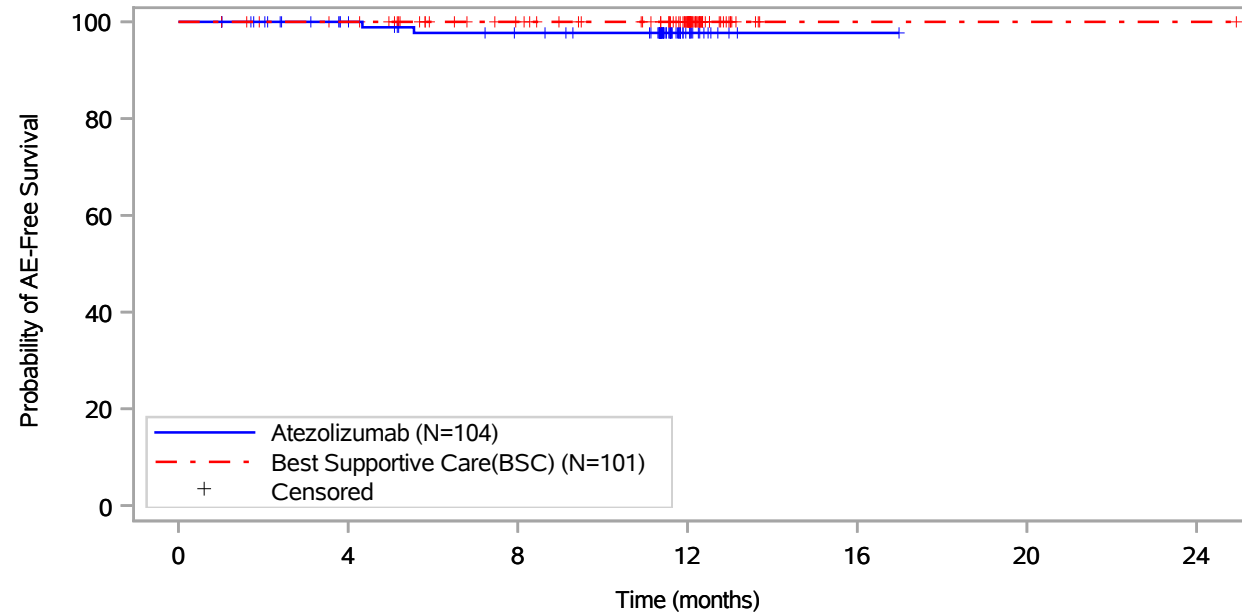
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



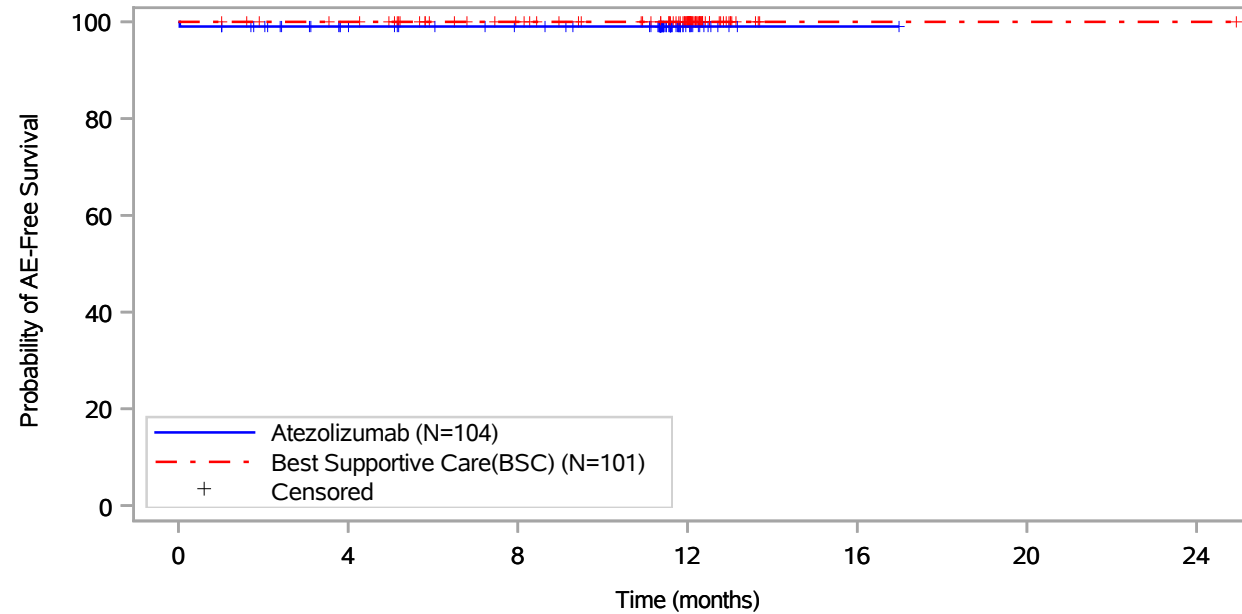
Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Immune system disorders, All



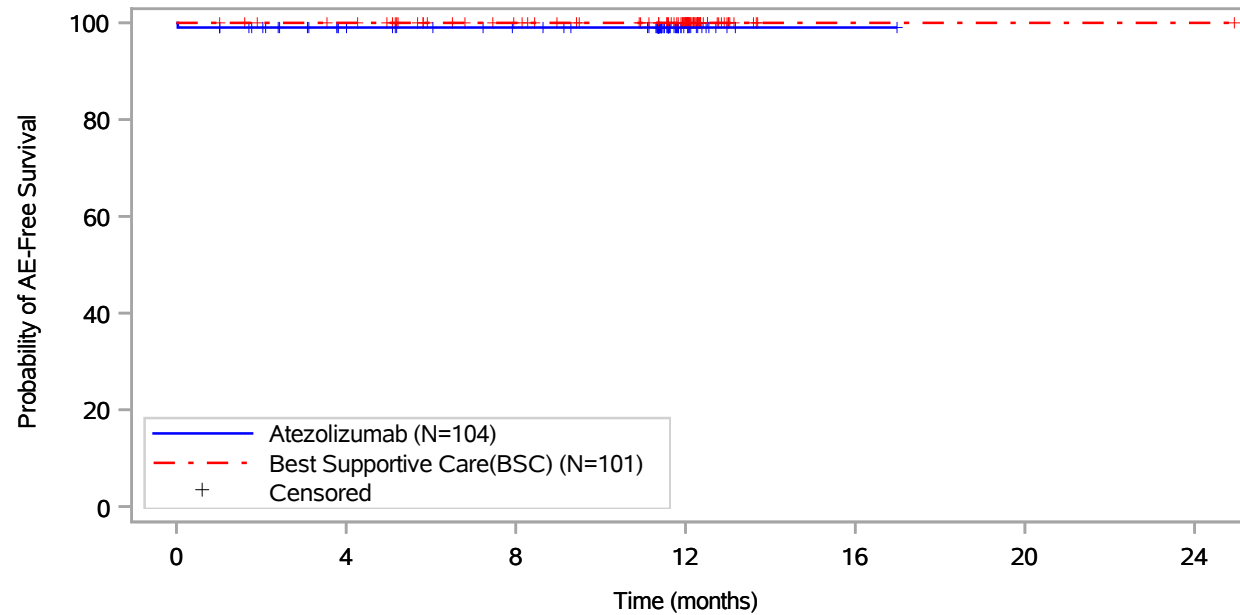
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Immune system disorders, Hypersensitivity



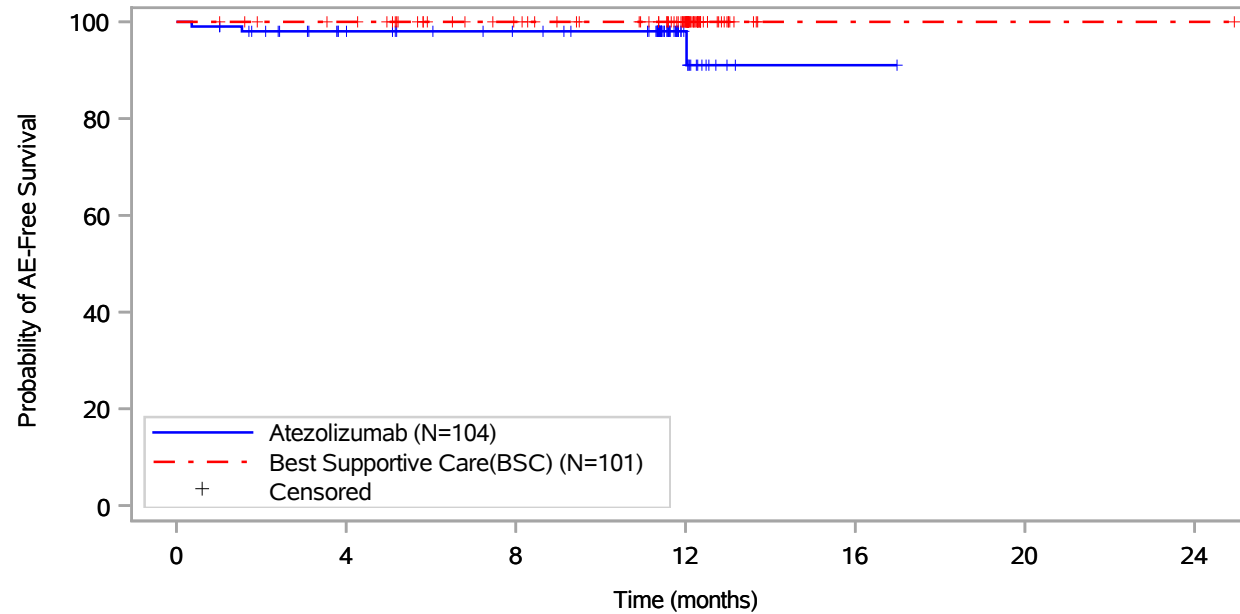
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Infections and infestations, All



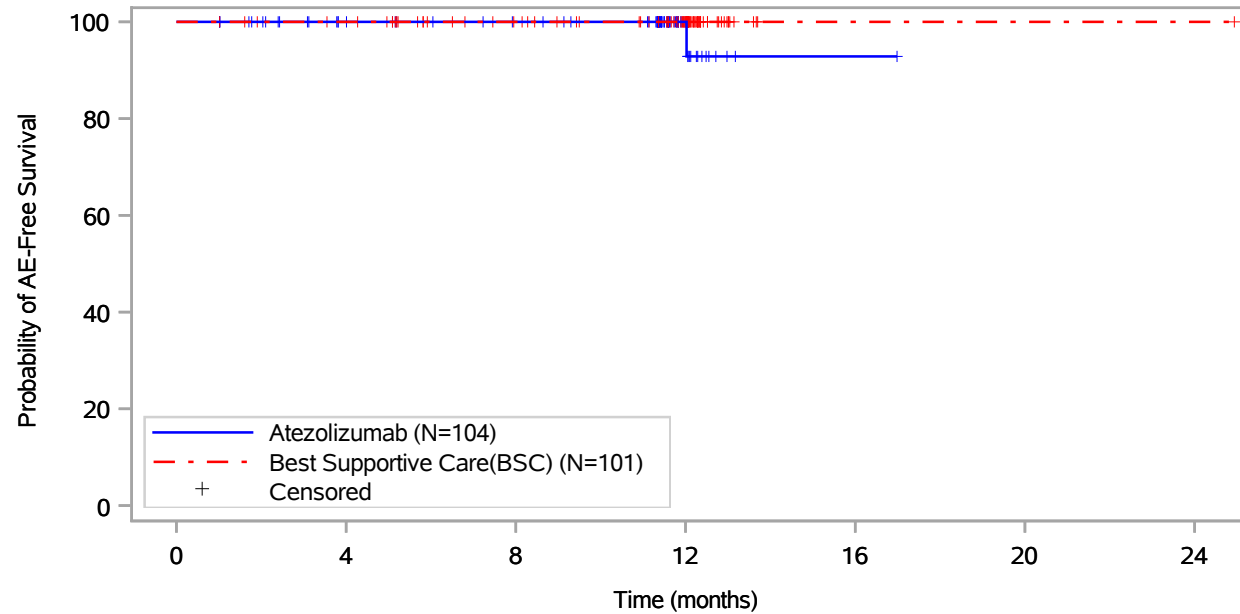
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	13	20	88	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Infections and infestations, Cellulitis



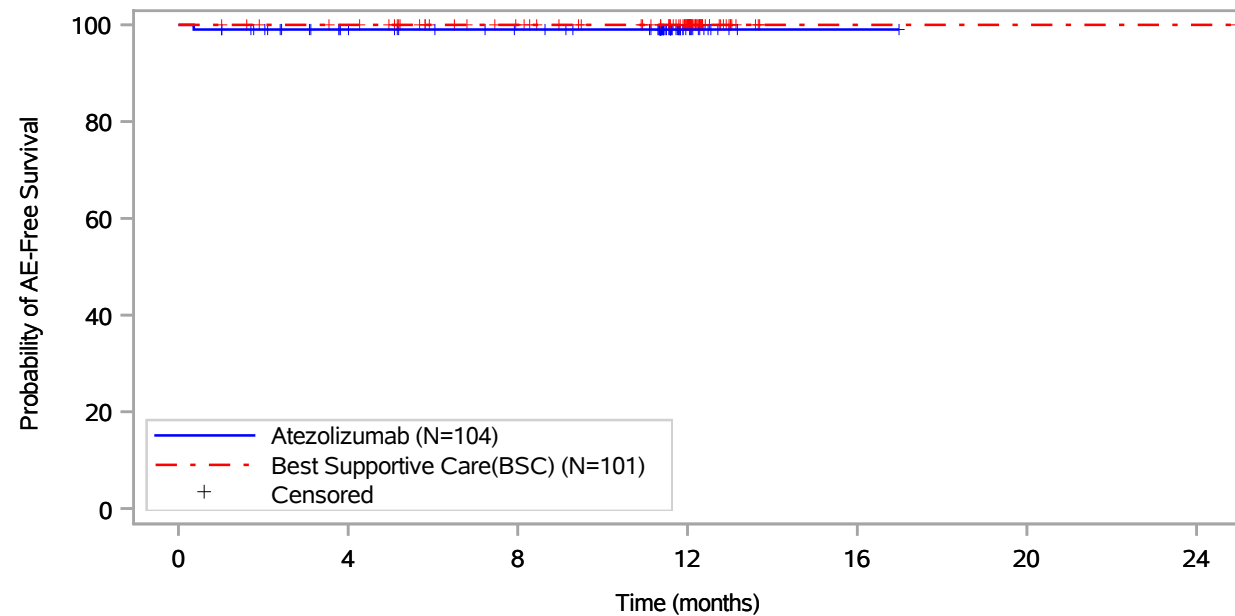
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Infections and infestations, Encephalitis



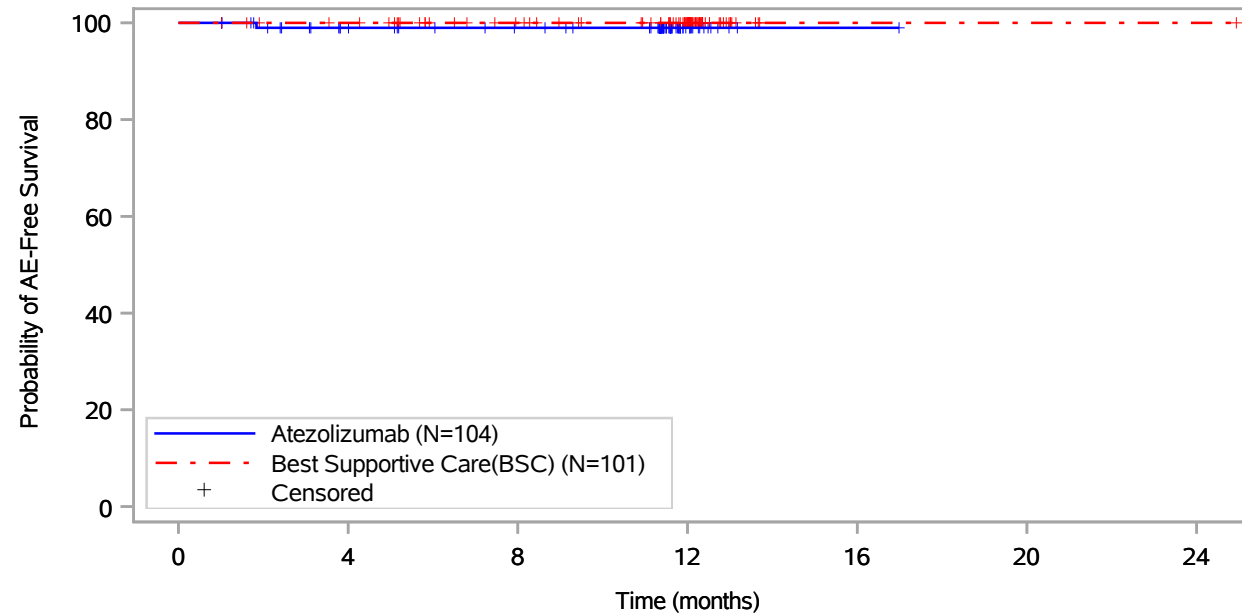
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Infections and infestations, Kidney infection



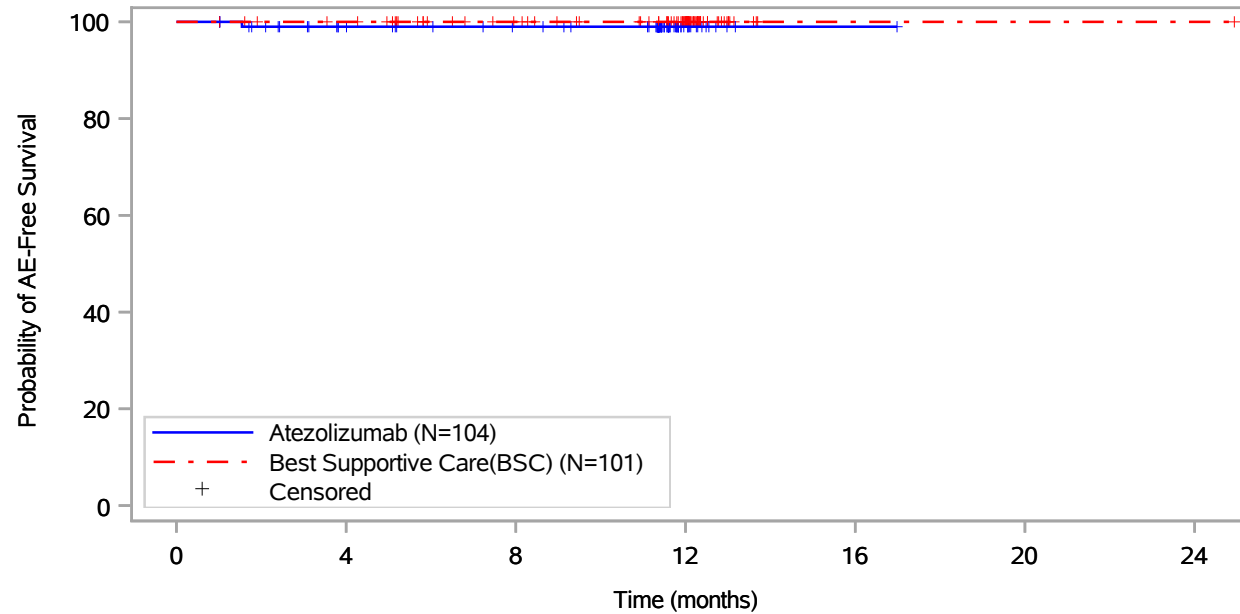
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Infections and infestations, Meningitis



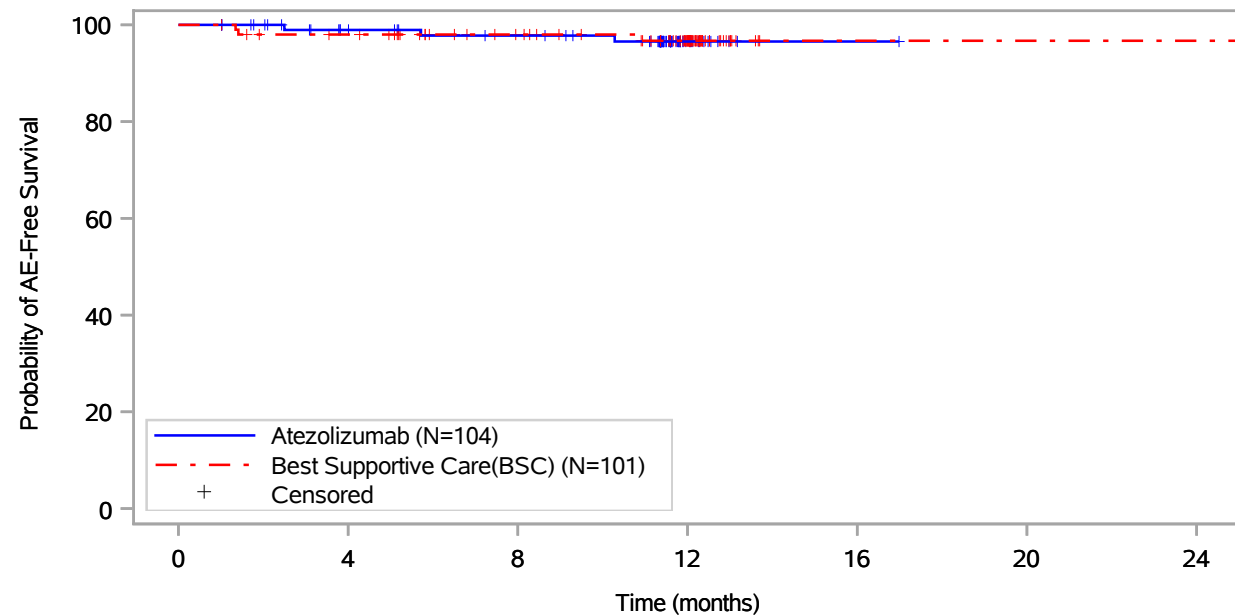
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Investigations, All



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	97	97	97

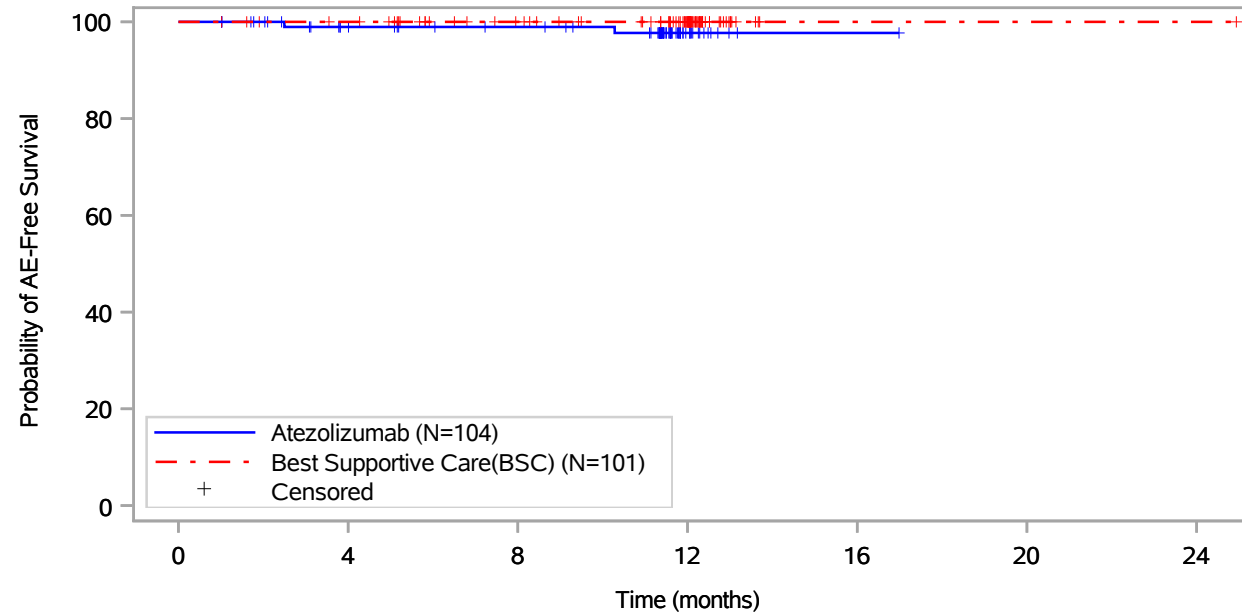
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	83	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	20	88	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

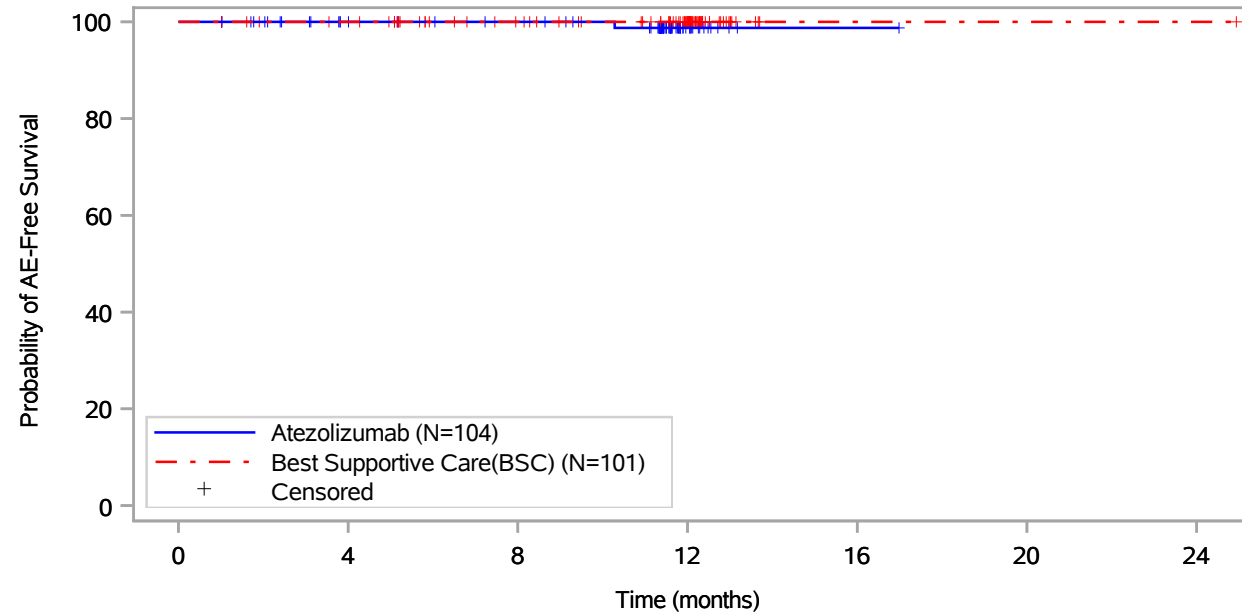
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	83	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

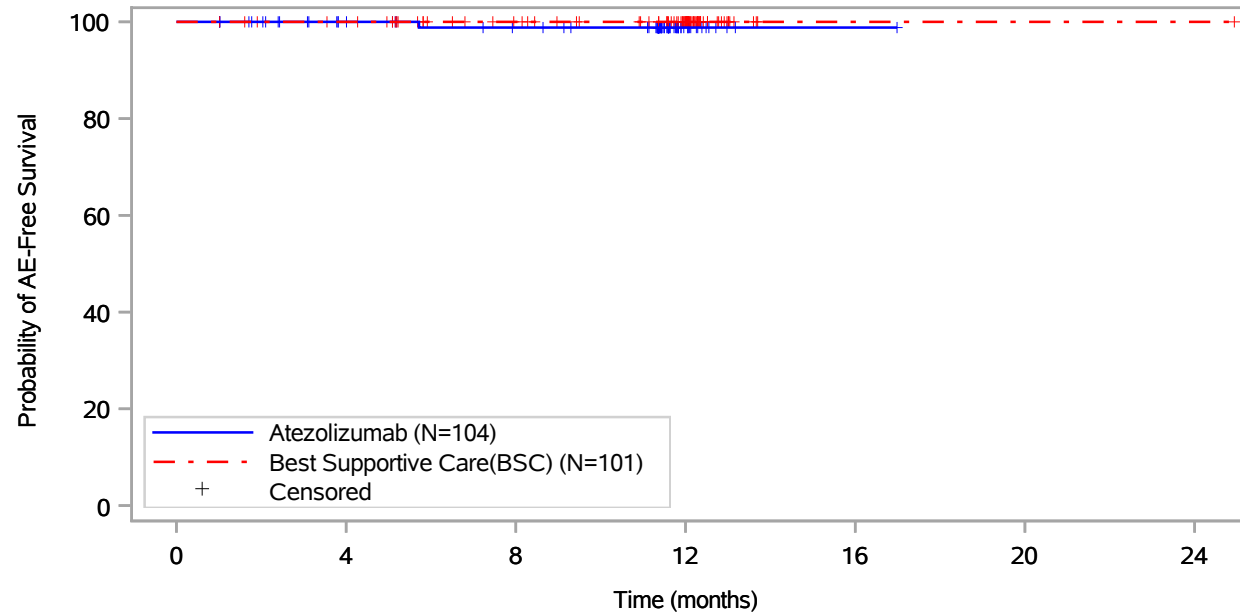
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Investigations, Gamma-glutamyltransferase increased



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

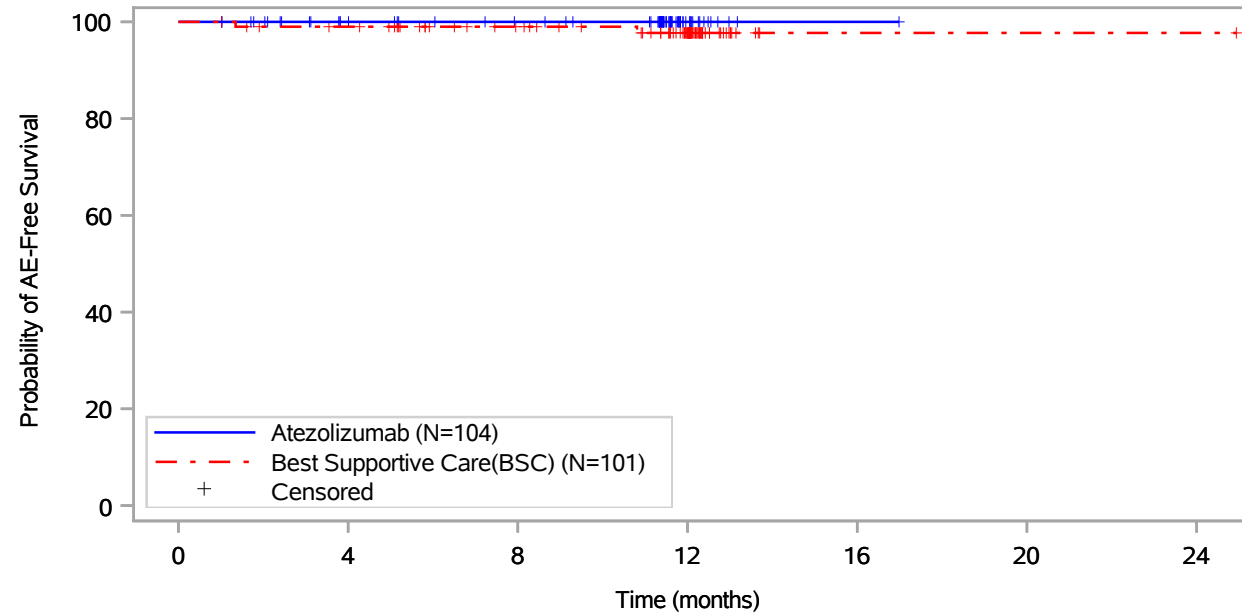
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Investigations, Neutrophil count decreased



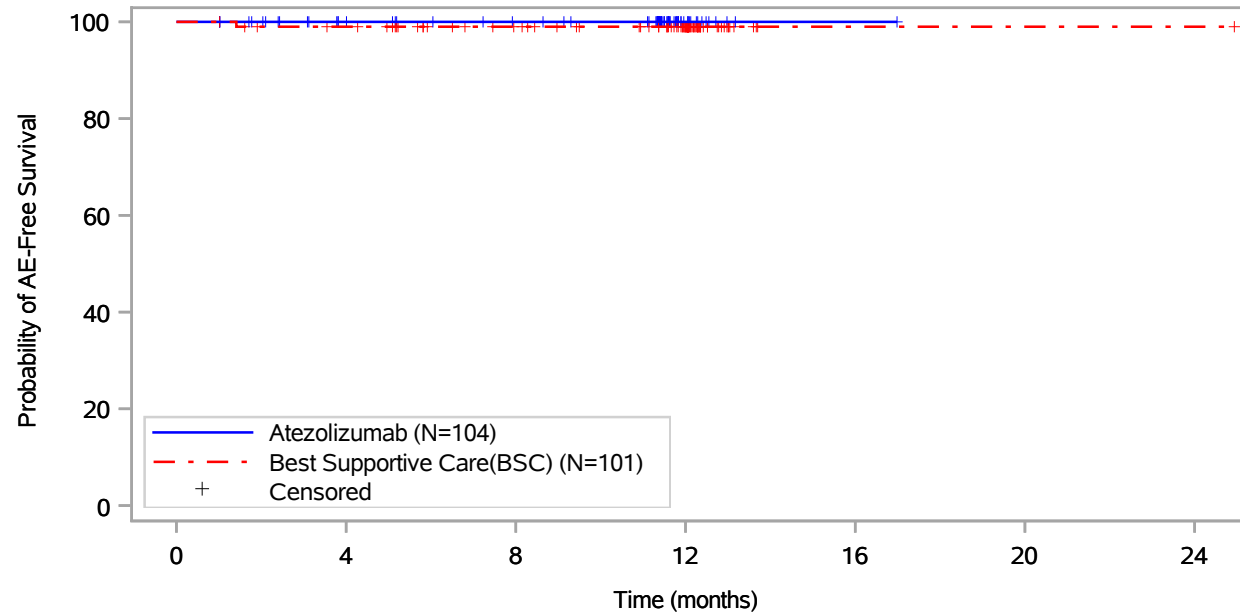
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	44	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Investigations, Weight increased



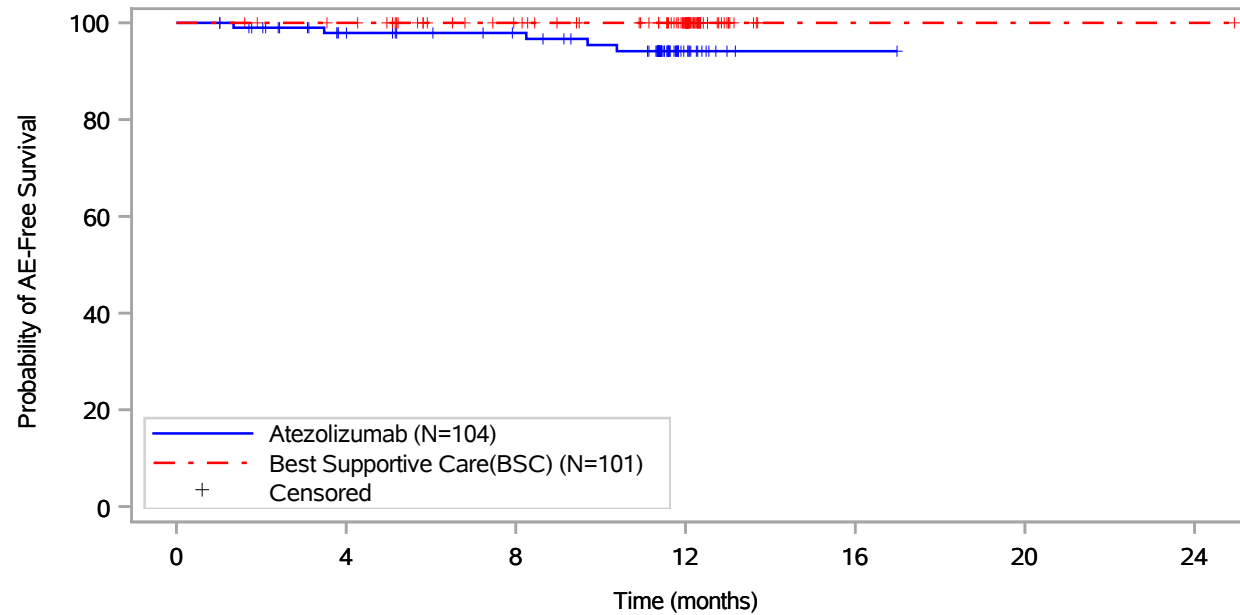
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Metabolism and nutrition disorders, All



Patients at risk							
Atezolizumab (N=104)	104	87	80	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	86	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

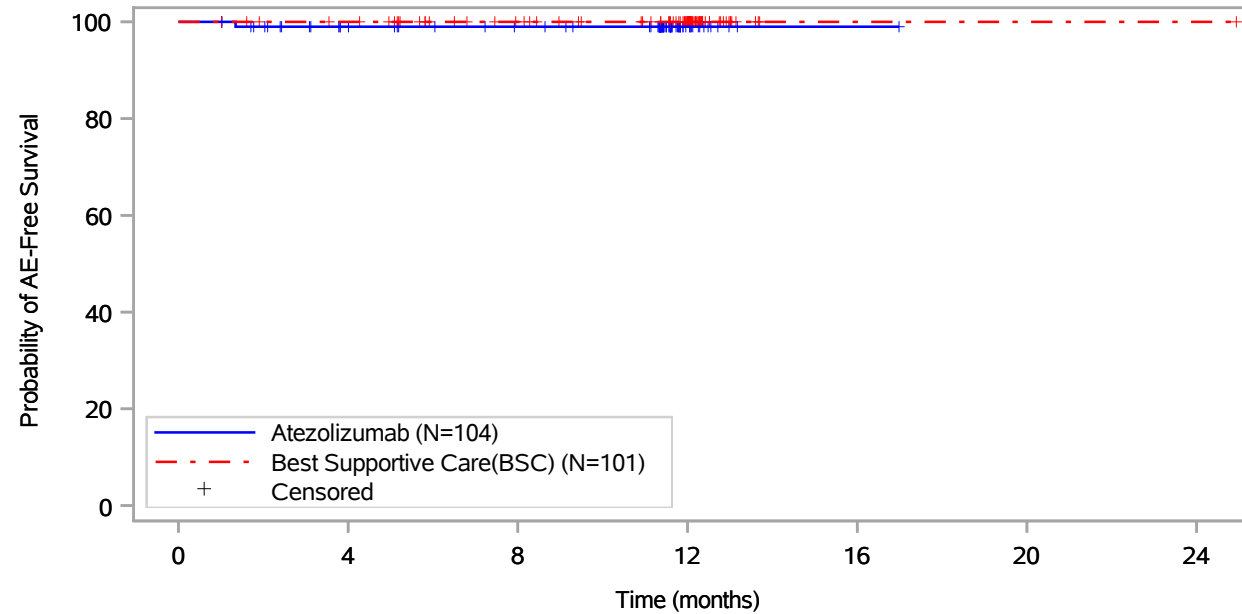
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

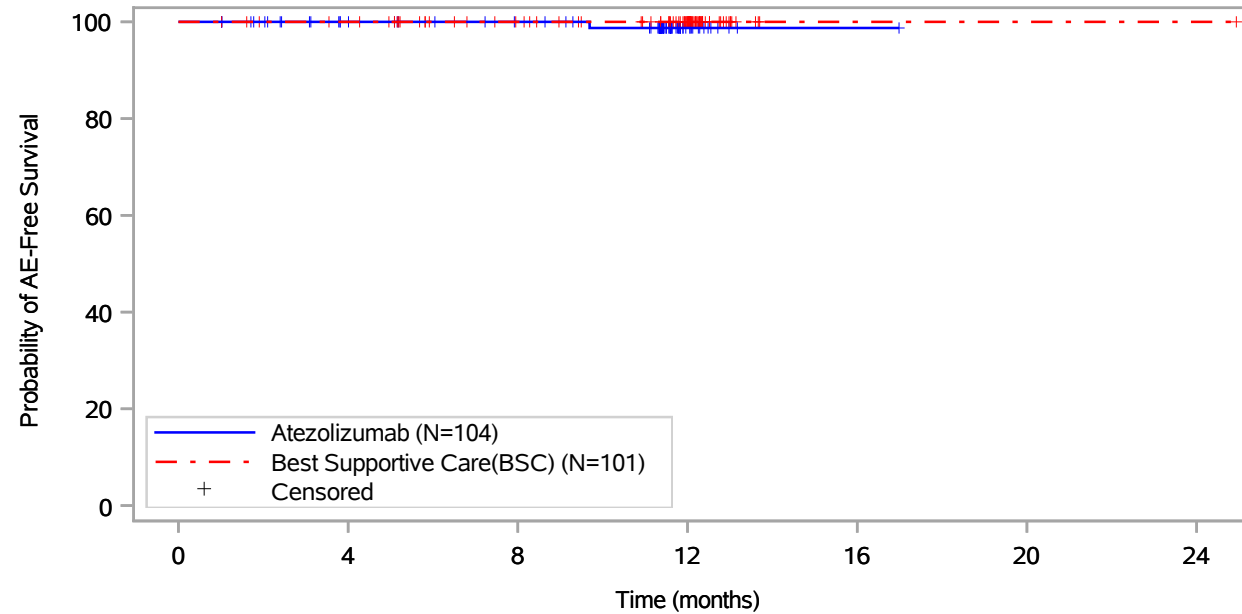
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	13	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

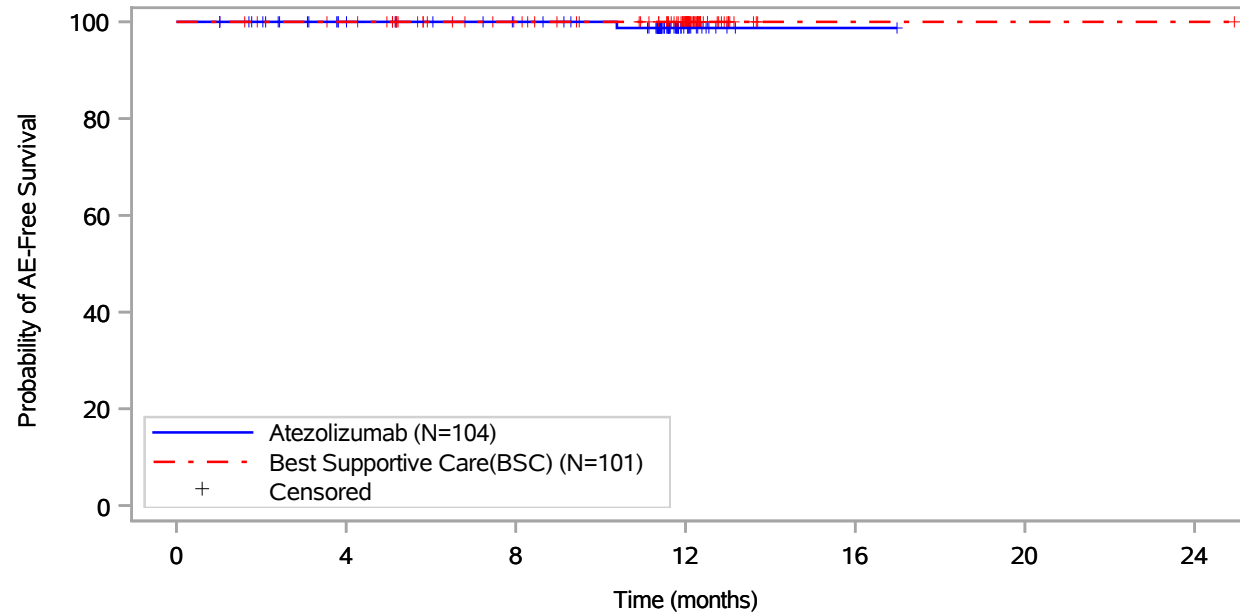
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

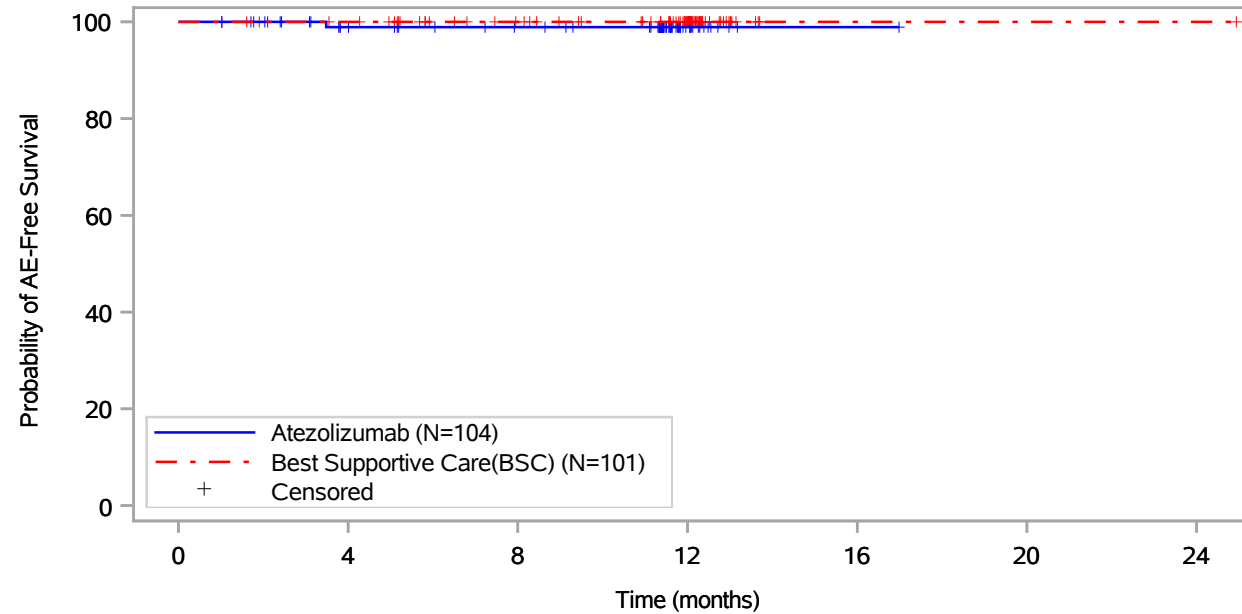
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

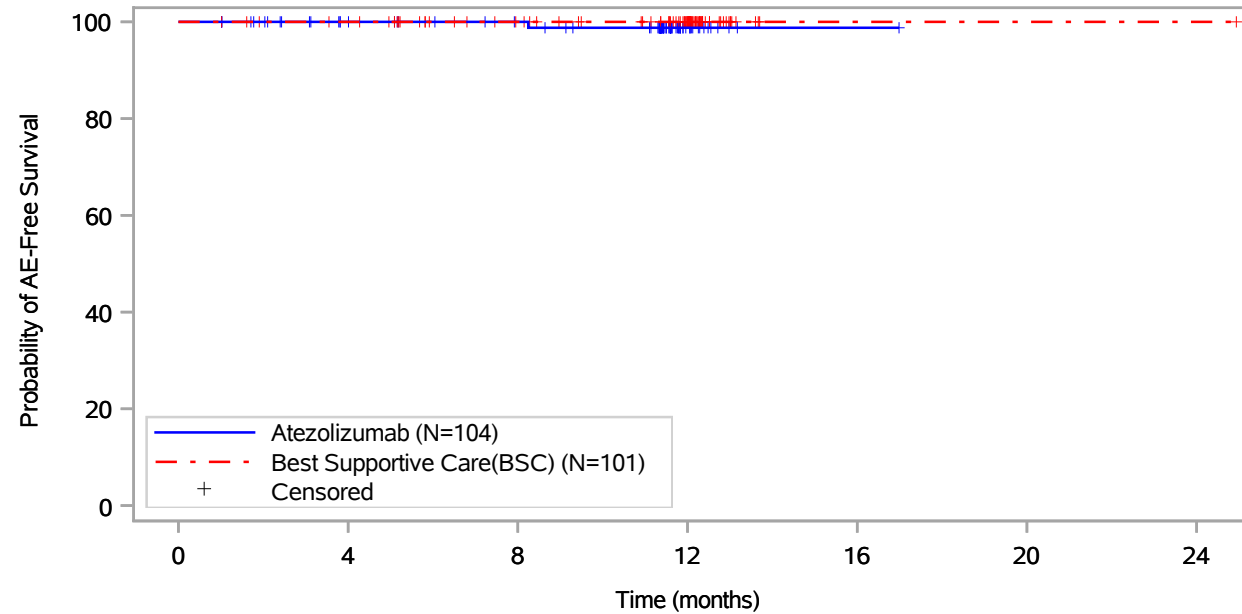
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 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

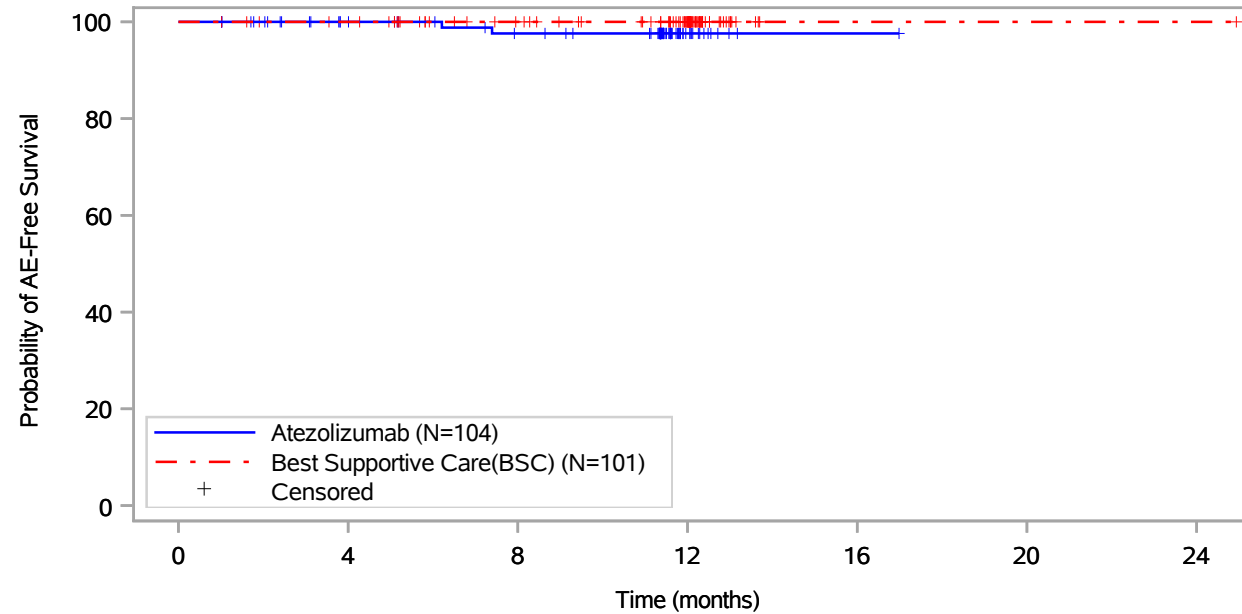
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	80	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

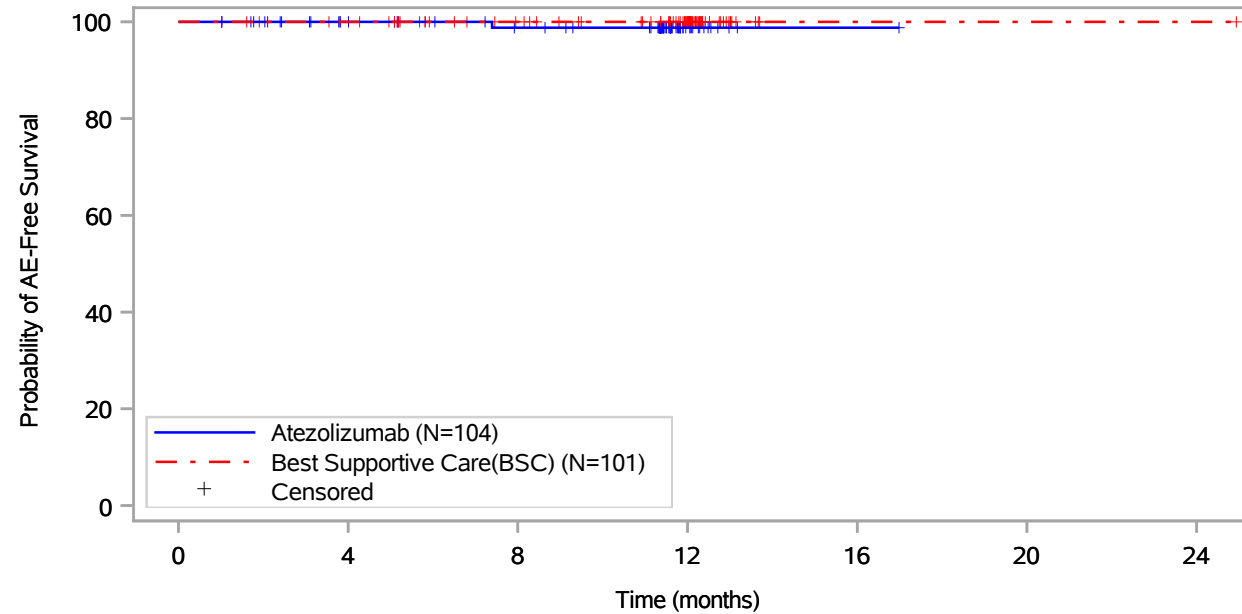
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

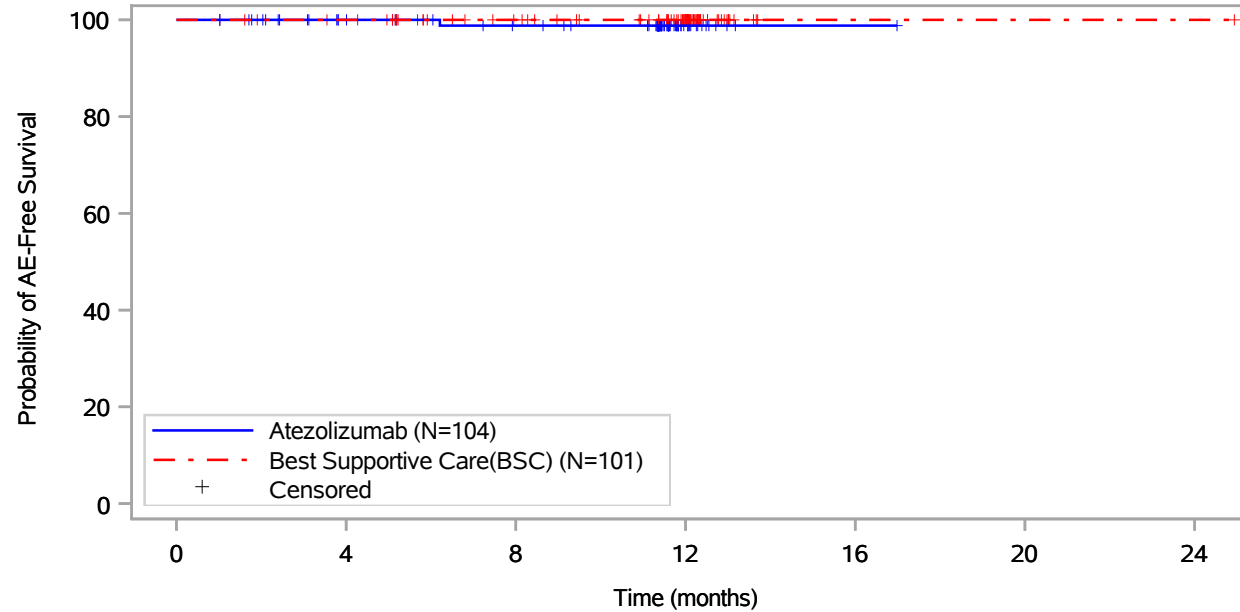
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

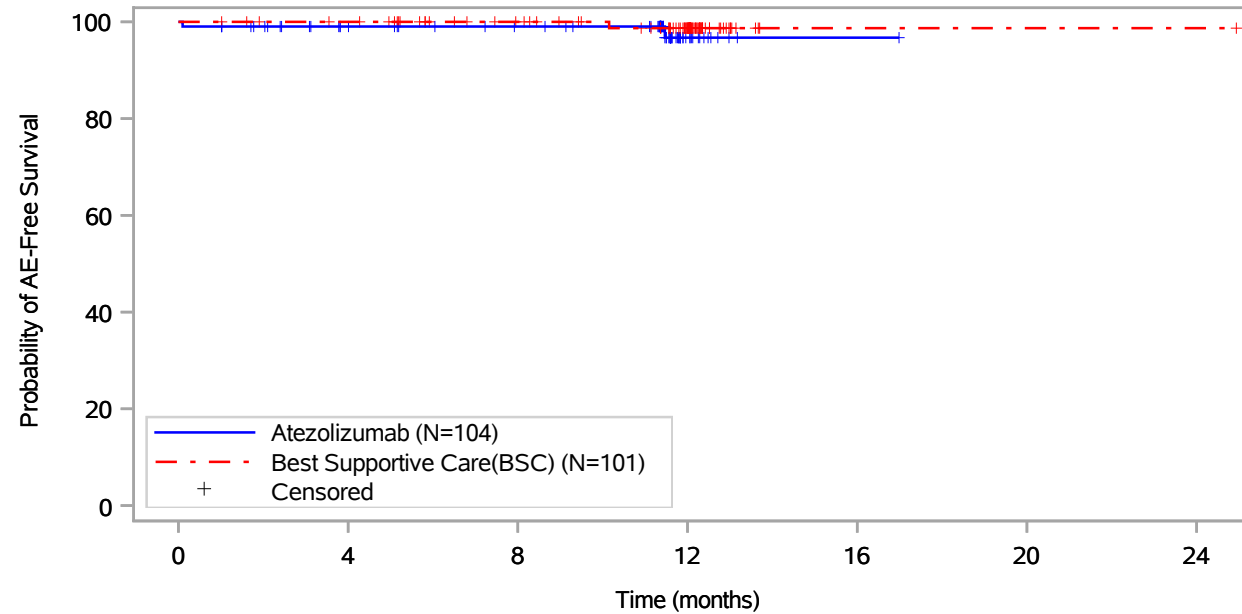
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

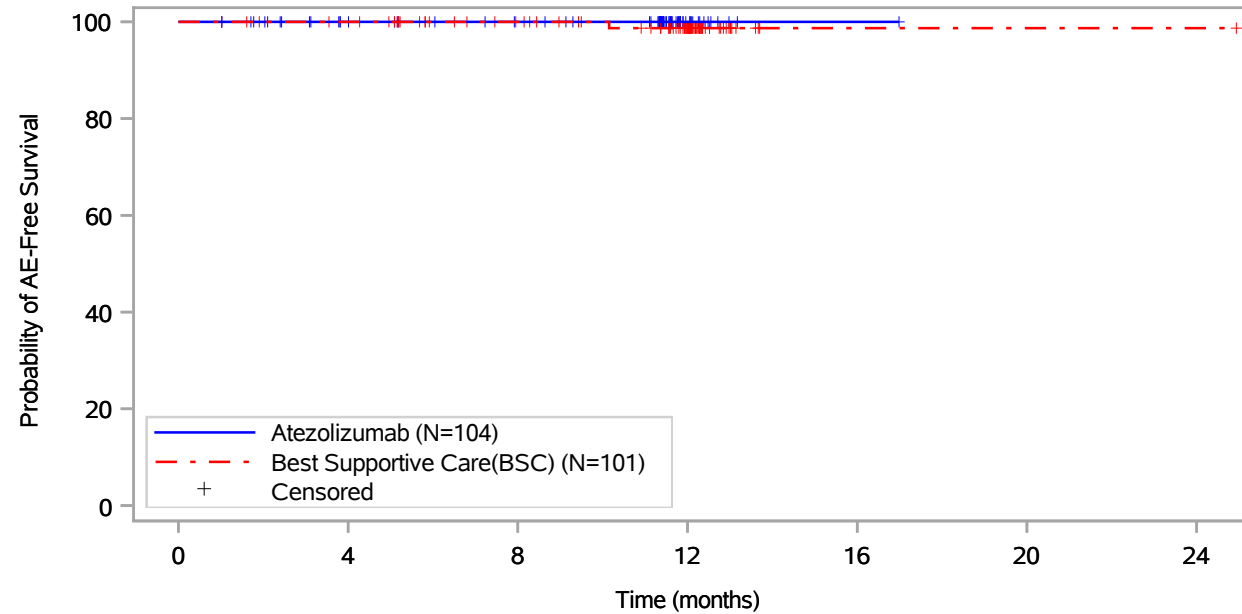
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

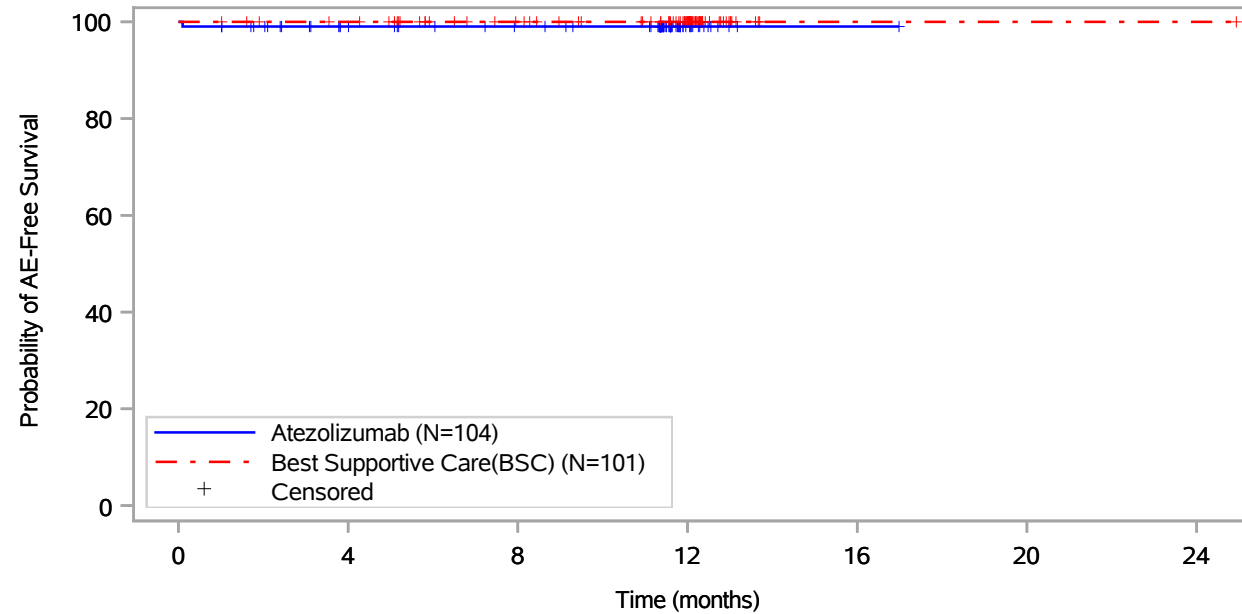
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

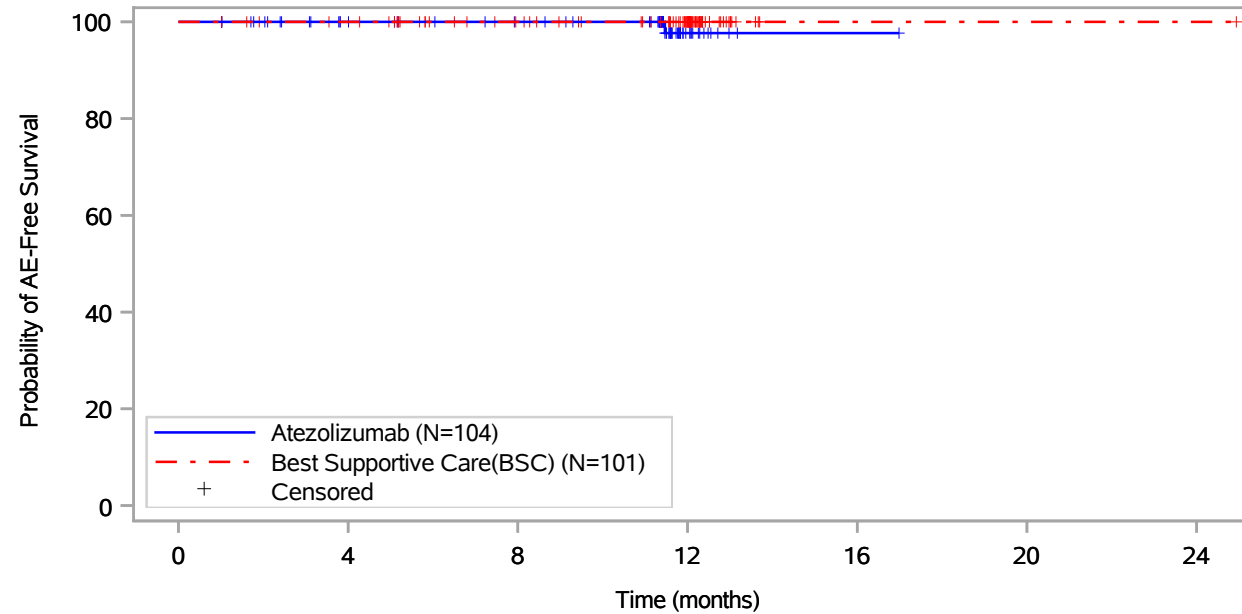
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



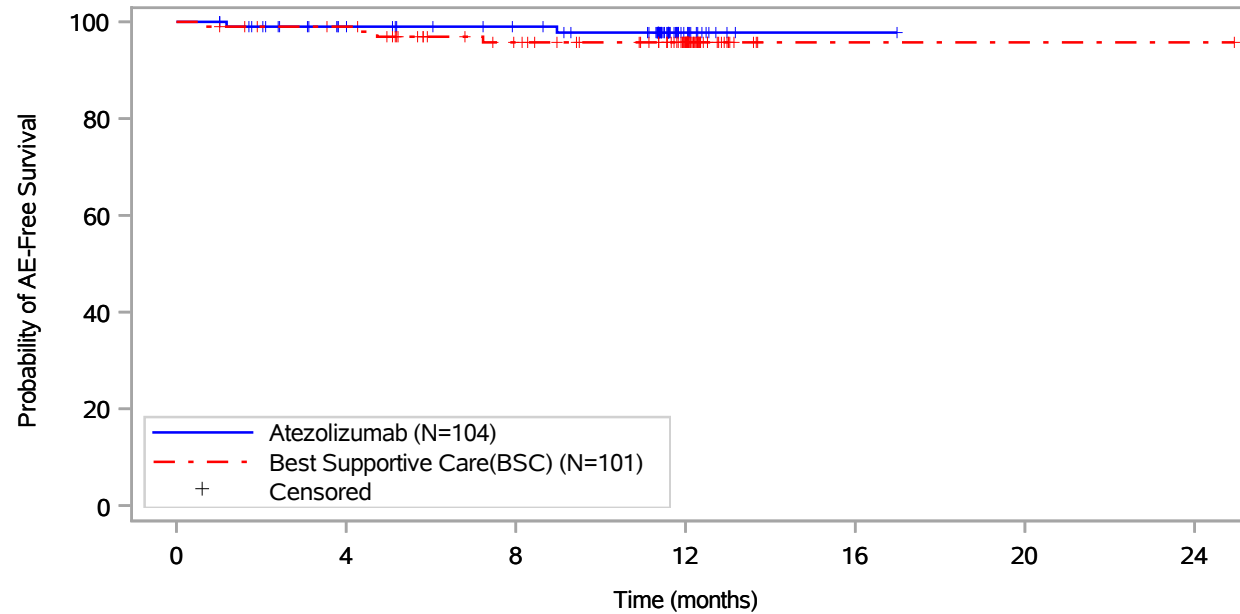
Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Nervous system disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	80	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	96	96	96

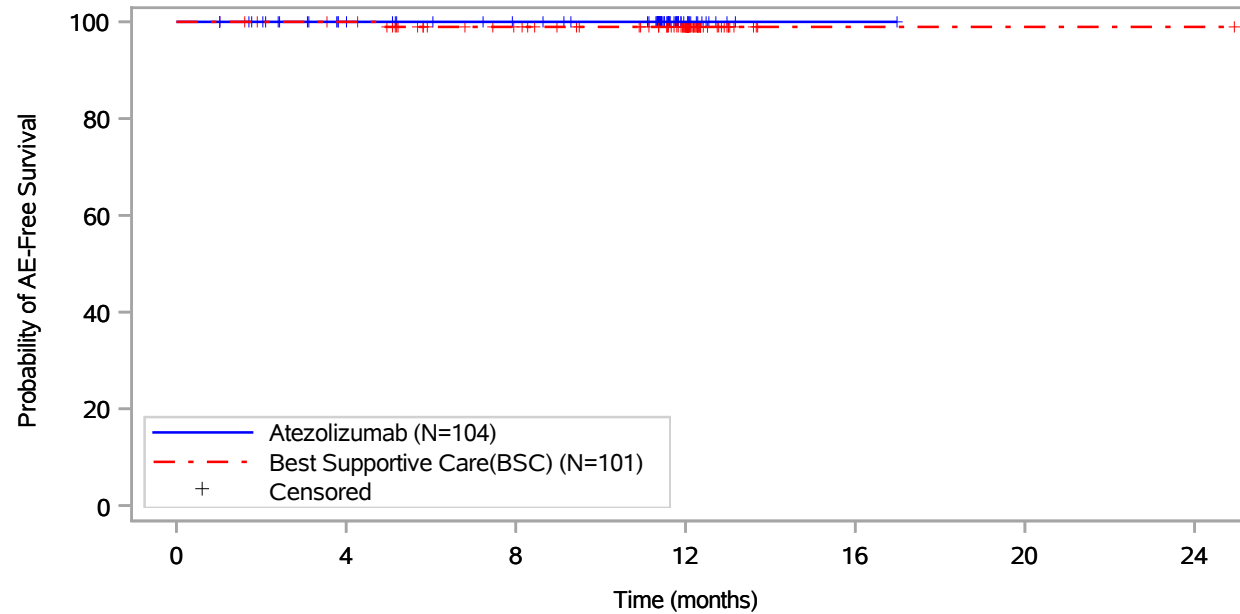
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Brain oedema



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	17	45	99	99	99

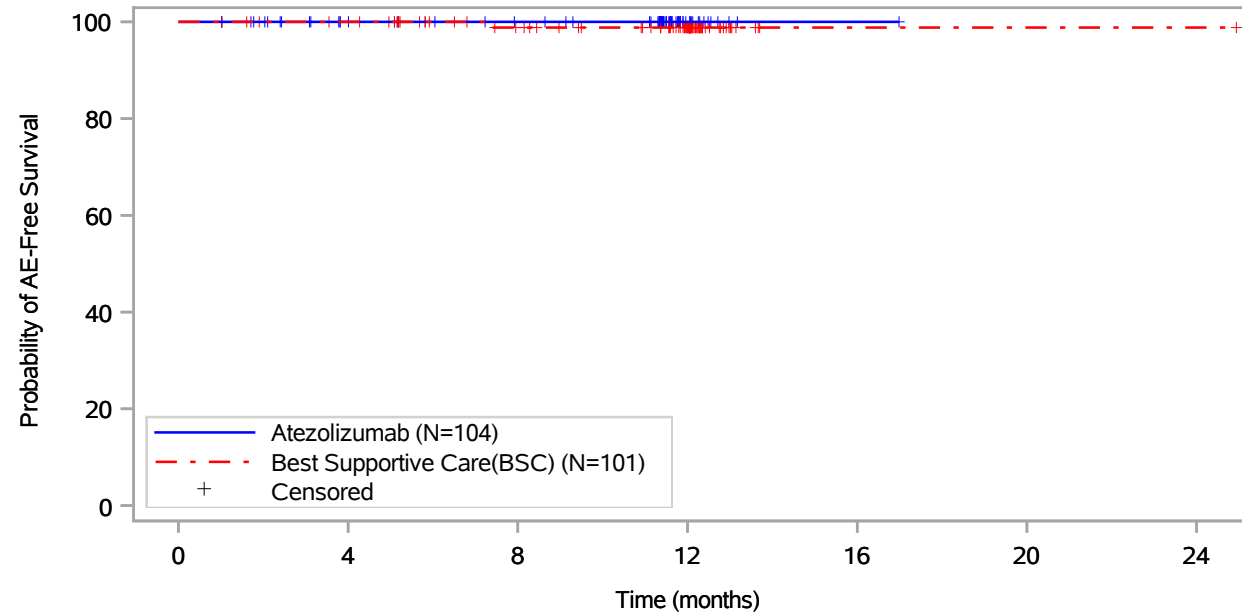
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

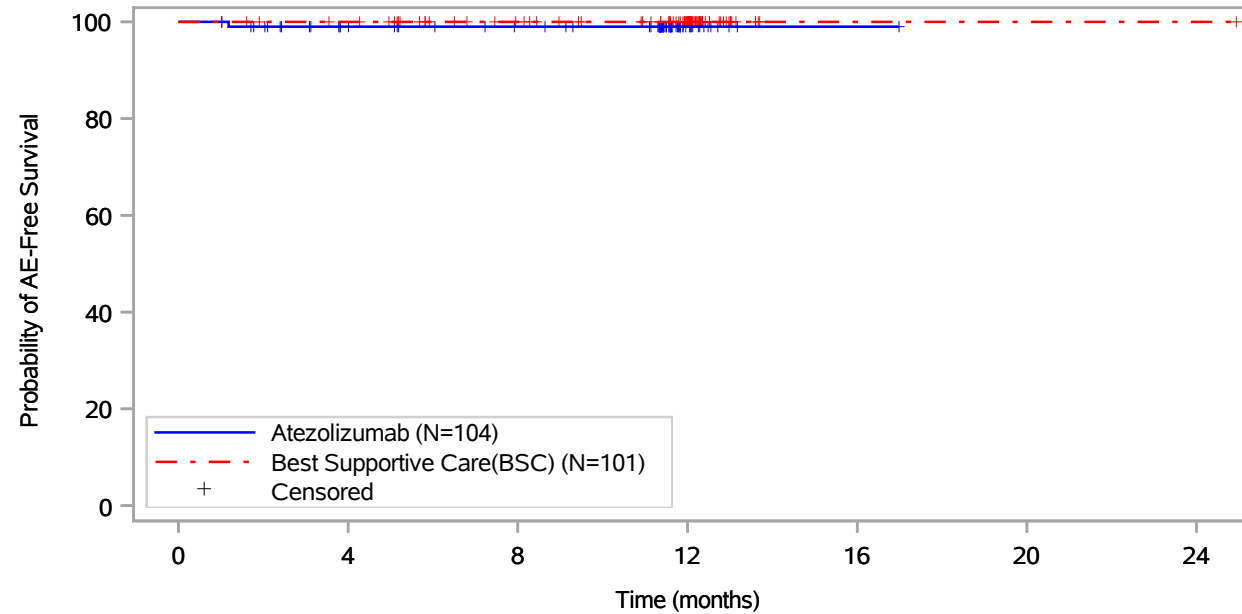
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

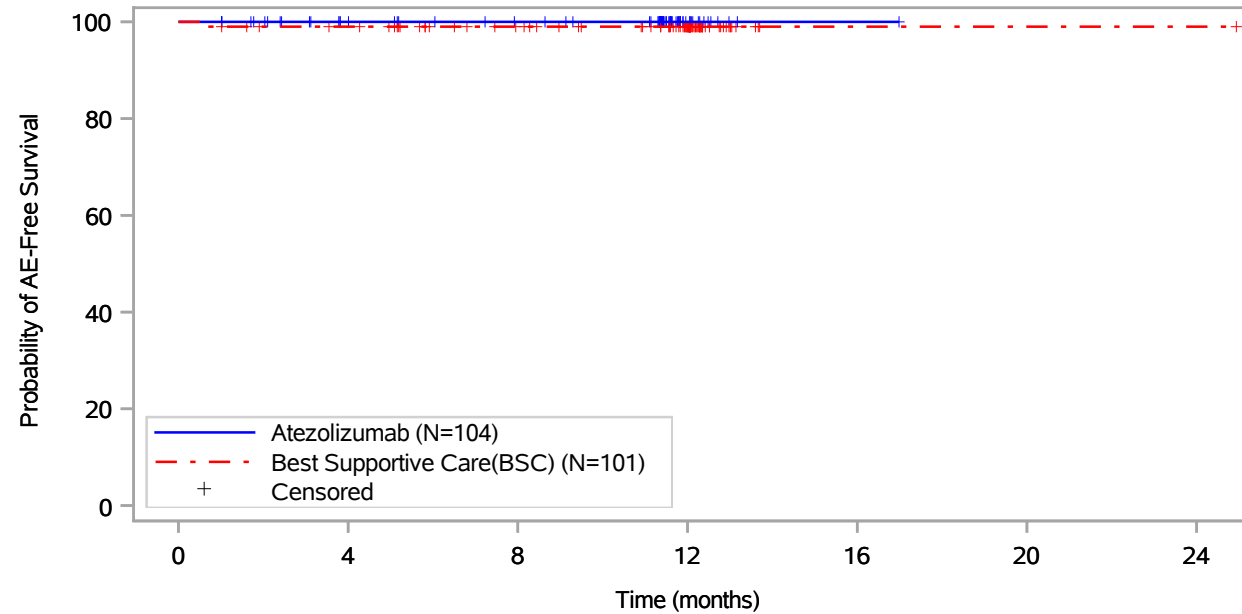
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Paraesthesia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

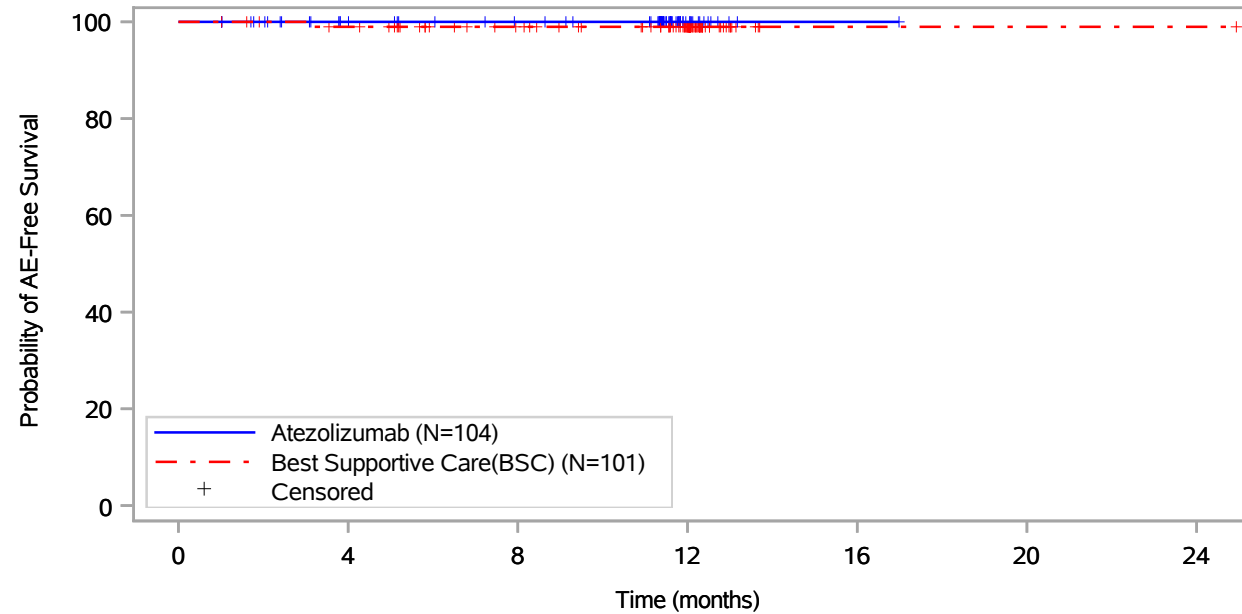
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

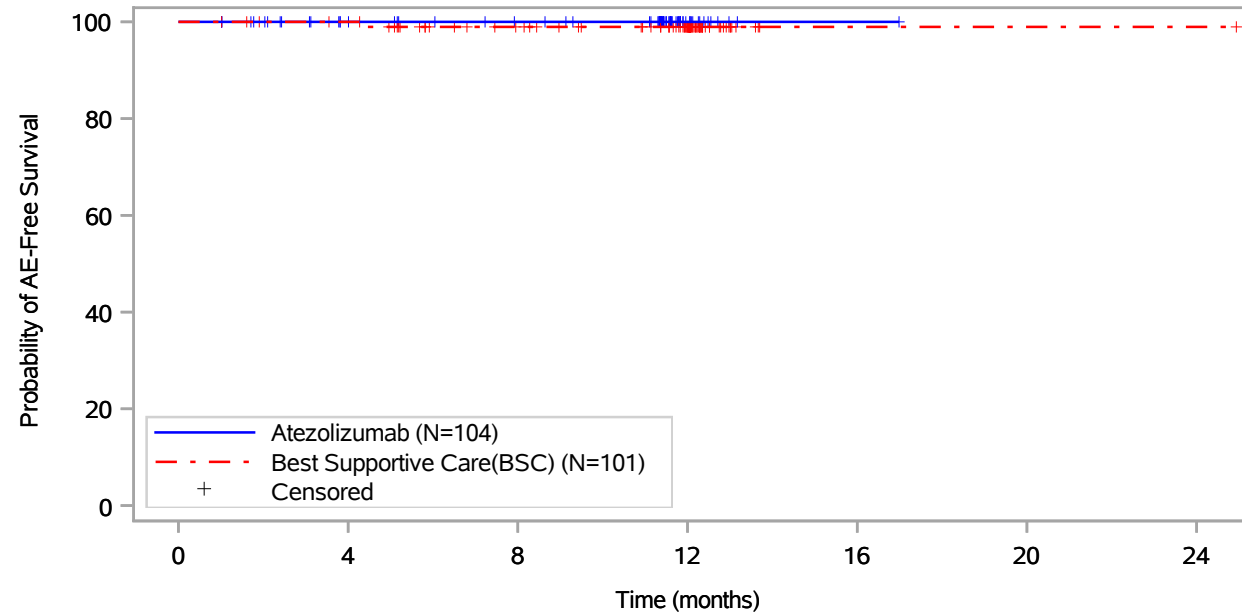
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



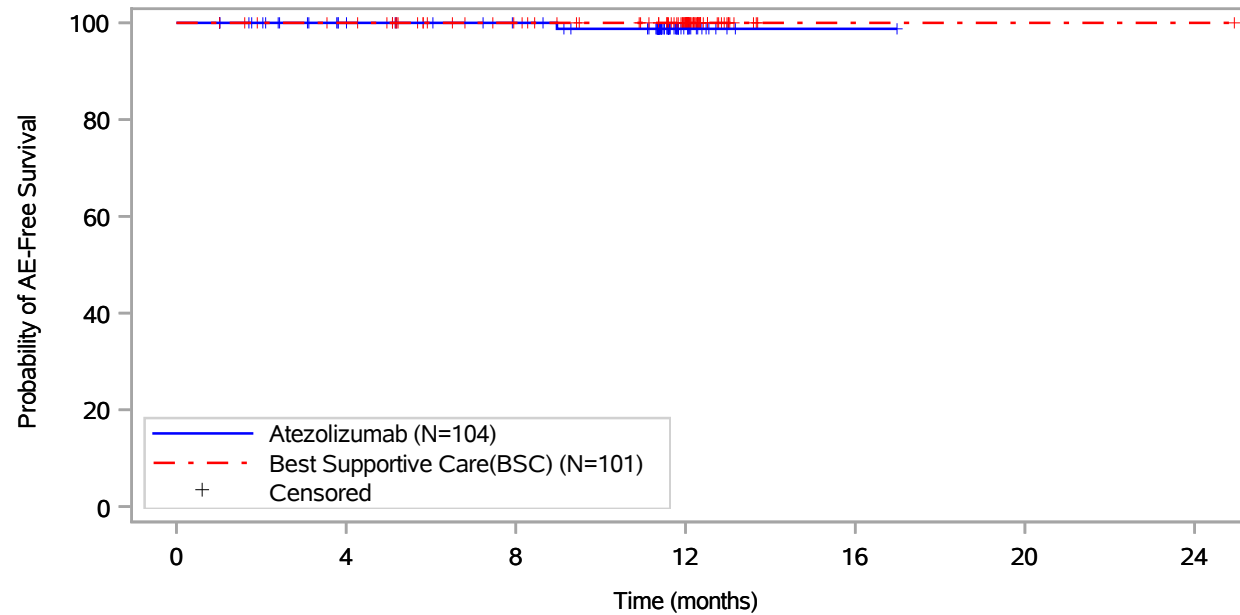
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	82	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Nervous system disorders, Syncope



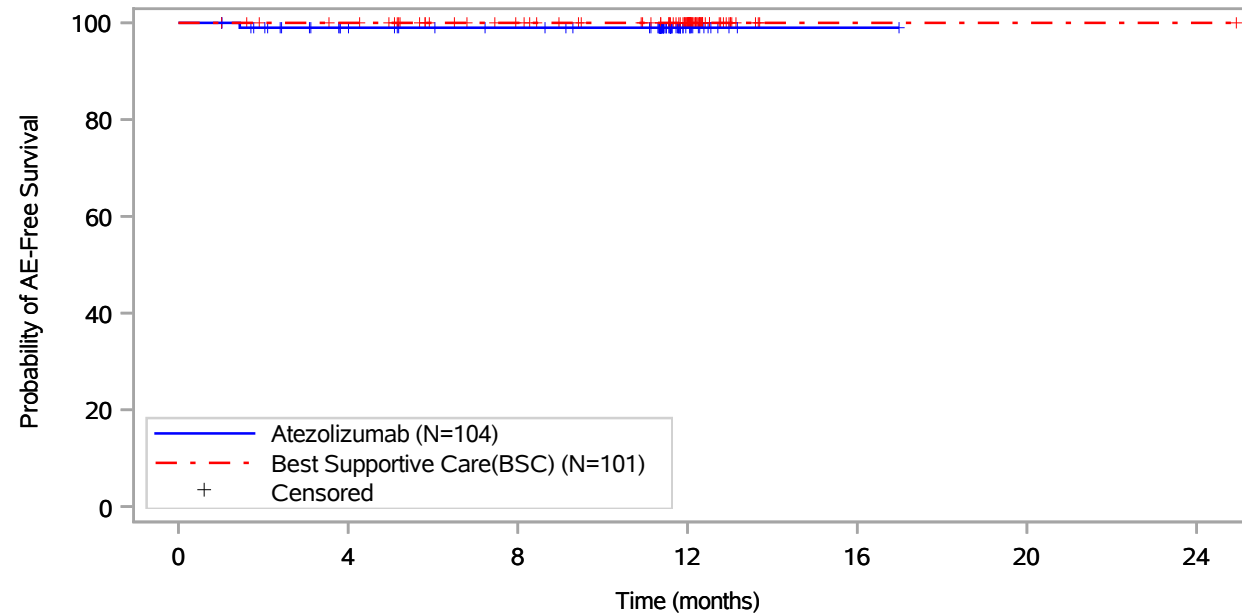
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Renal and urinary disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

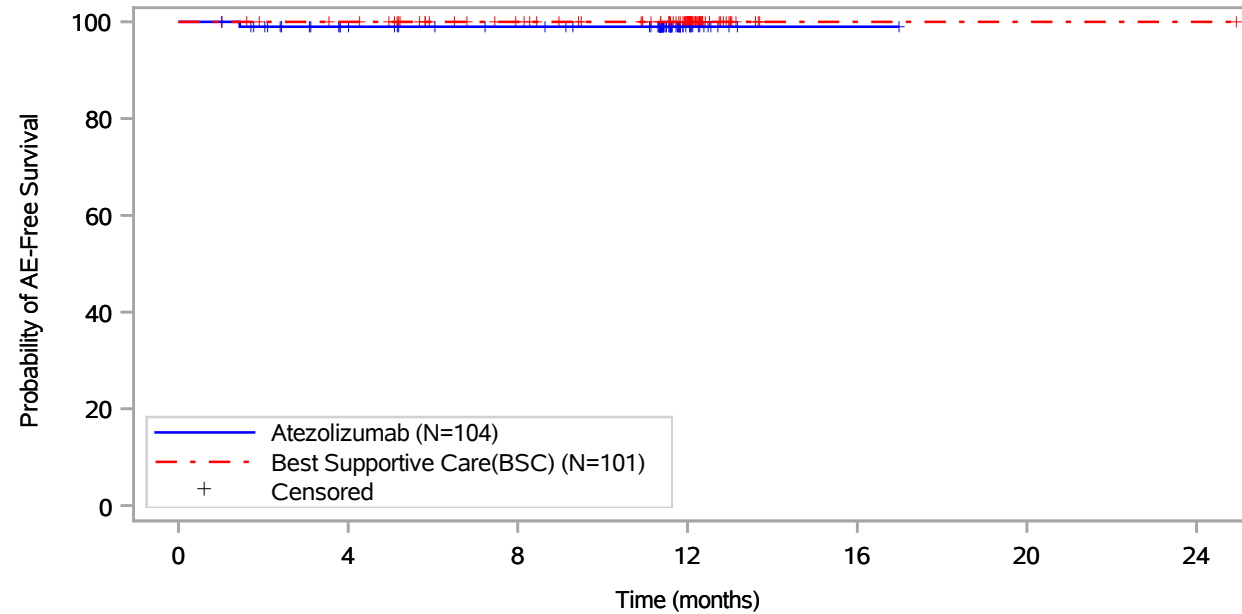
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 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

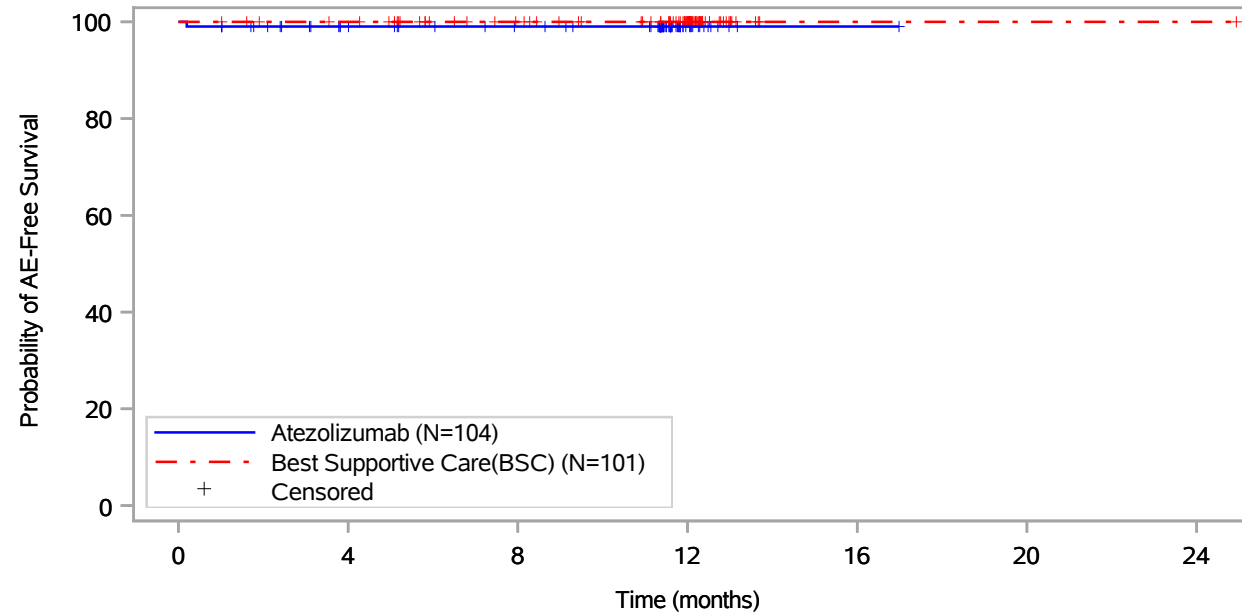
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

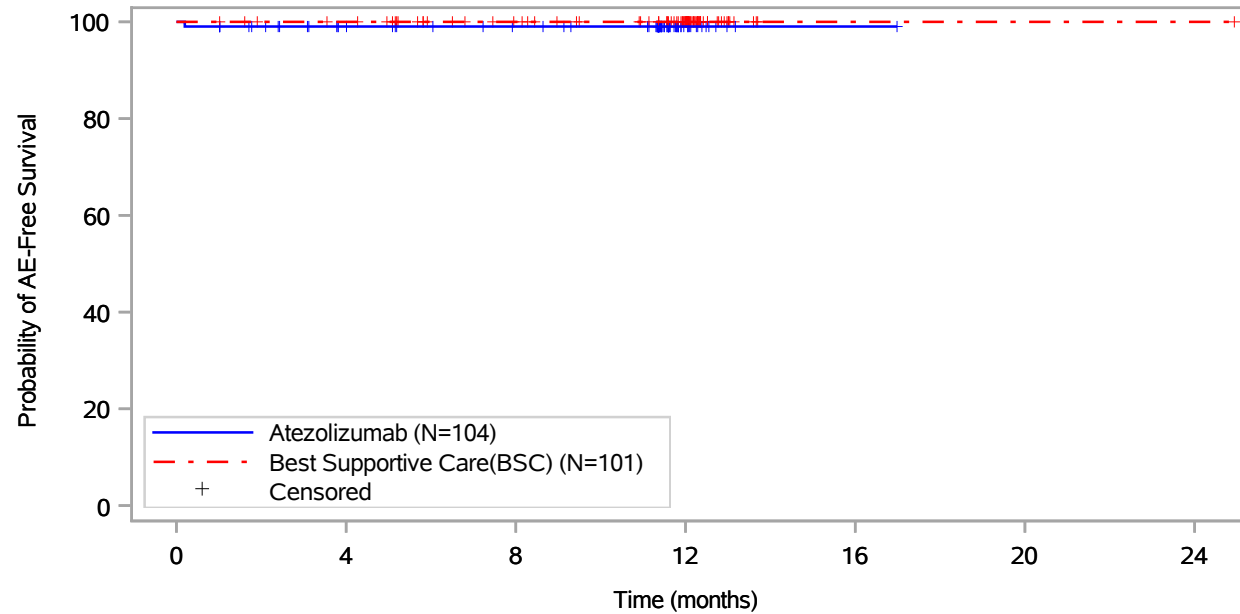
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

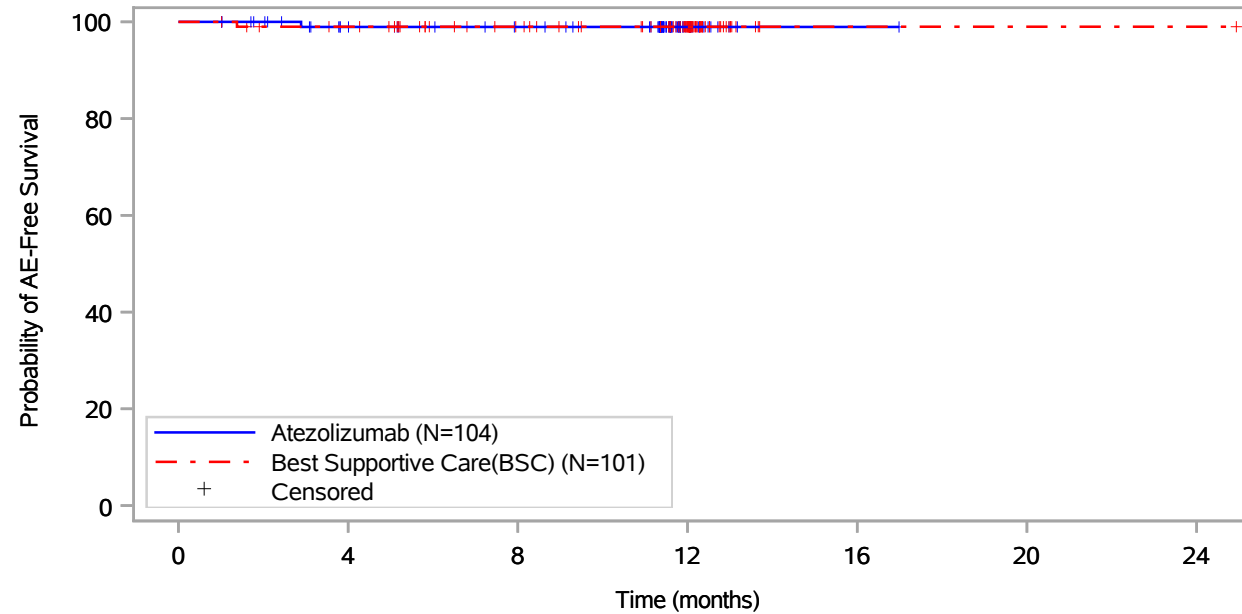
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

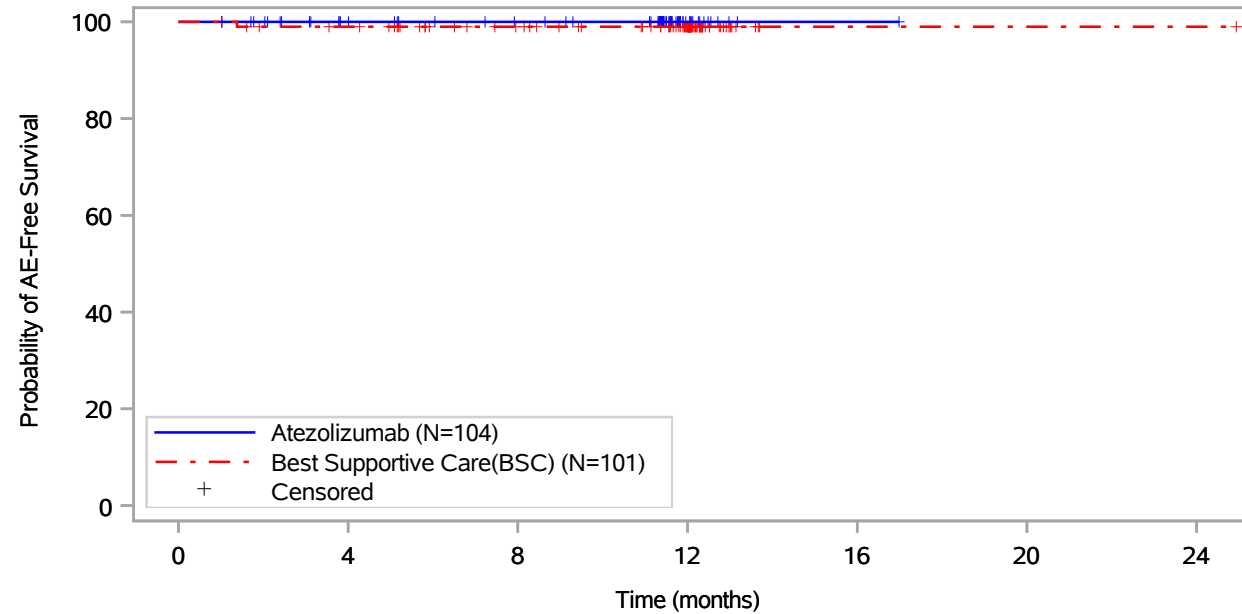
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

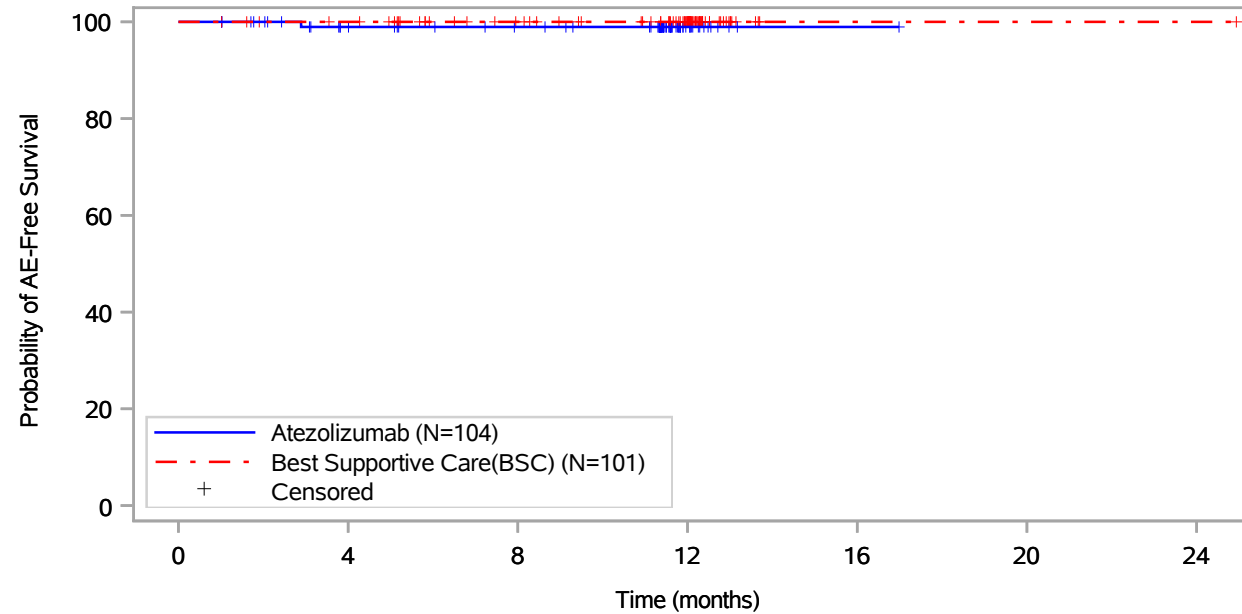
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

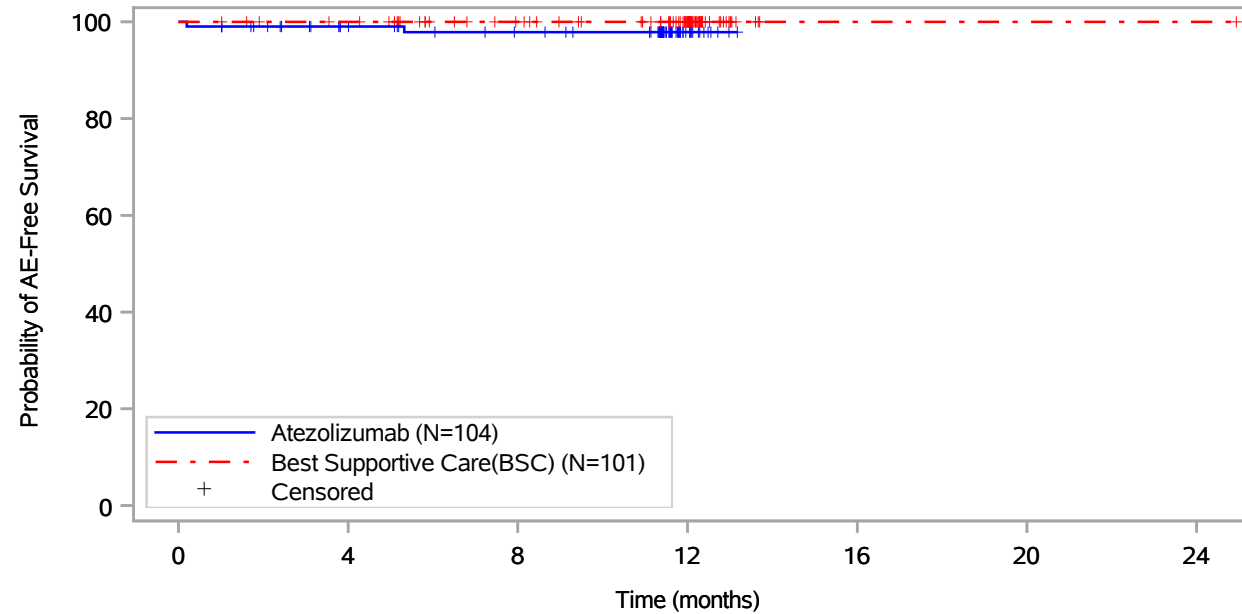
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

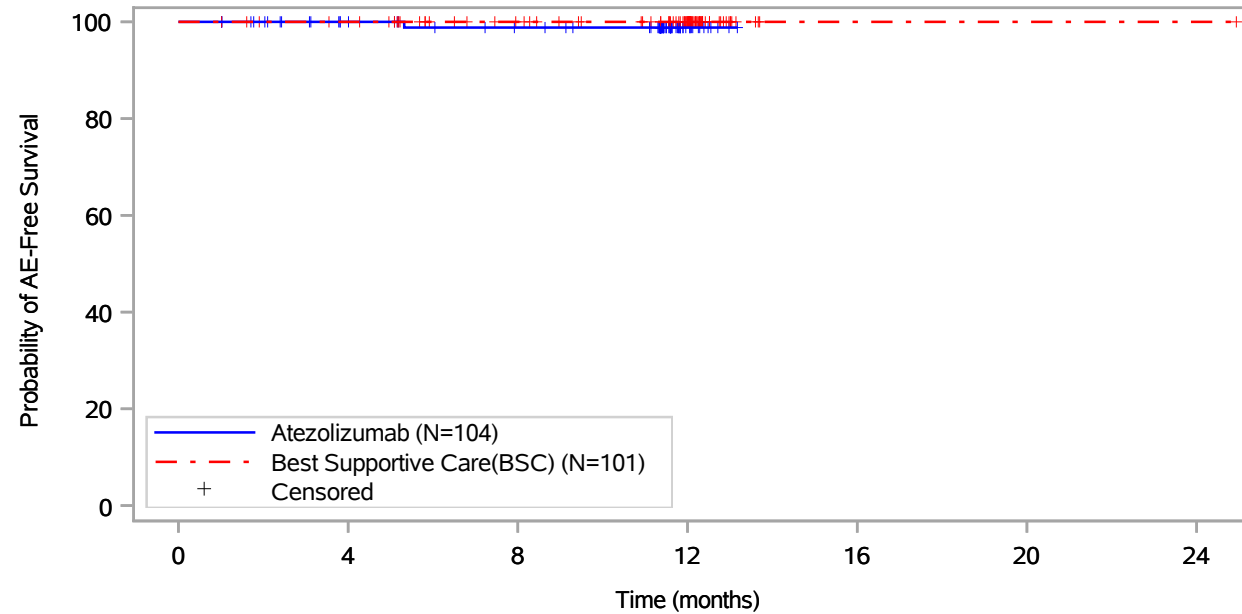
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk								
Atezolizumab (N=104)	104	89	81	13	NE	NE	NE	
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	
Patients censored								
Atezolizumab (N=104)	0	15	22	90	NE	NE	NE	
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	

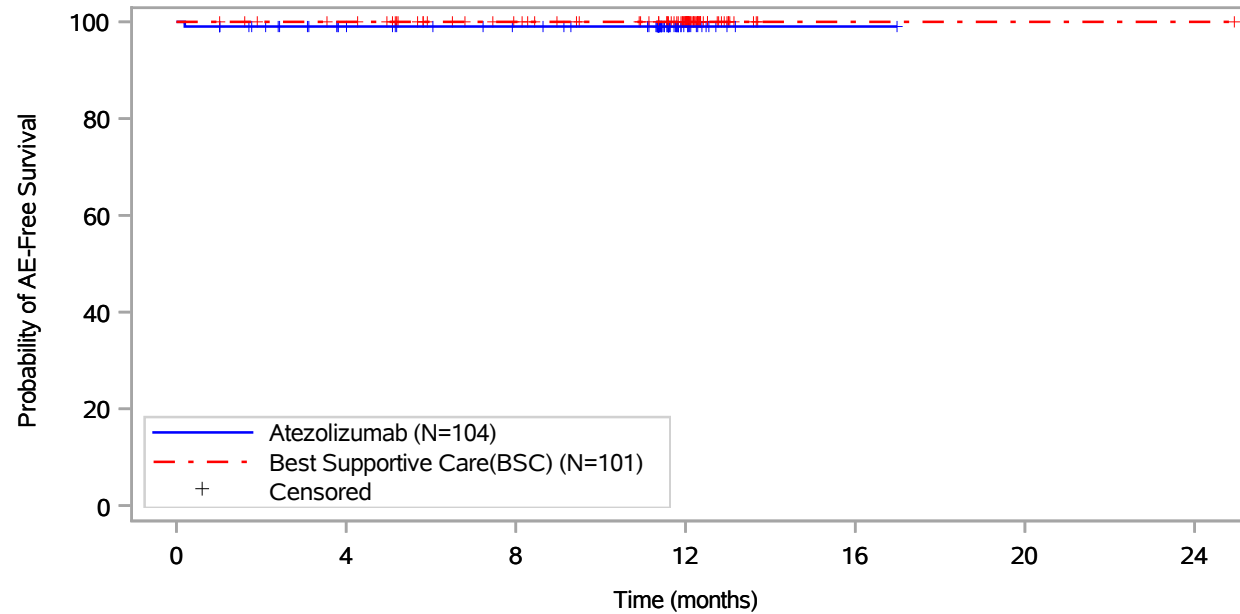
Includes adverse events occurring on or after the start of treatment in randomization period.
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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



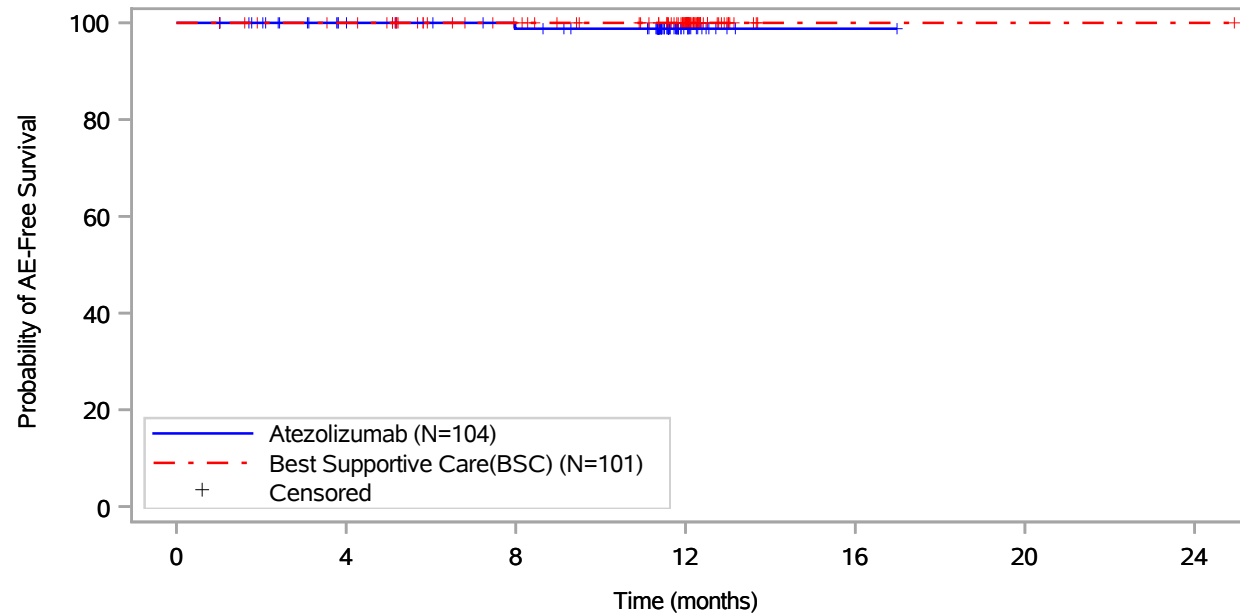
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:41

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Vascular disorders, All



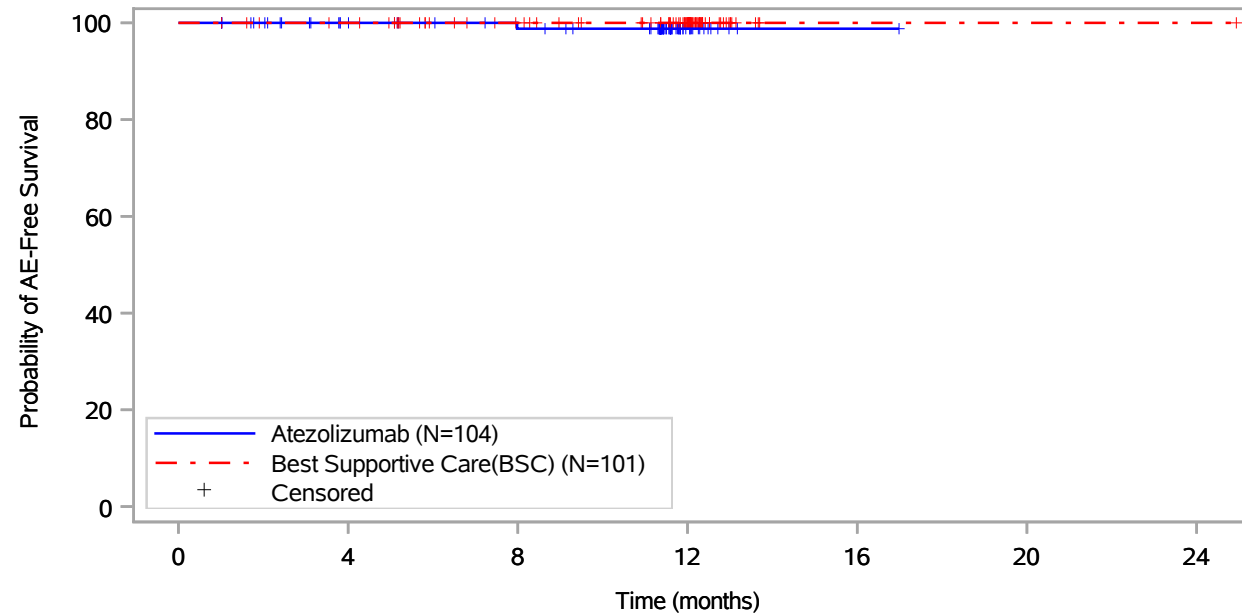
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3-5 Adverse Event
STUDY: GO29527
 Vascular disorders, Hypertension



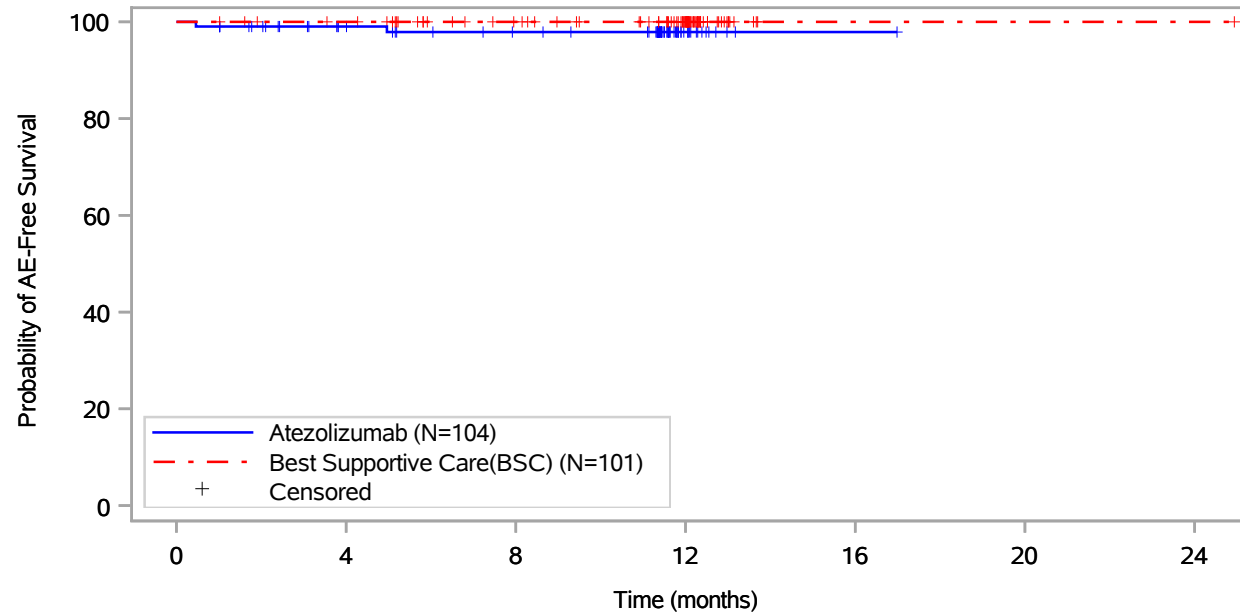
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Blood and lymphatic system disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	80	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

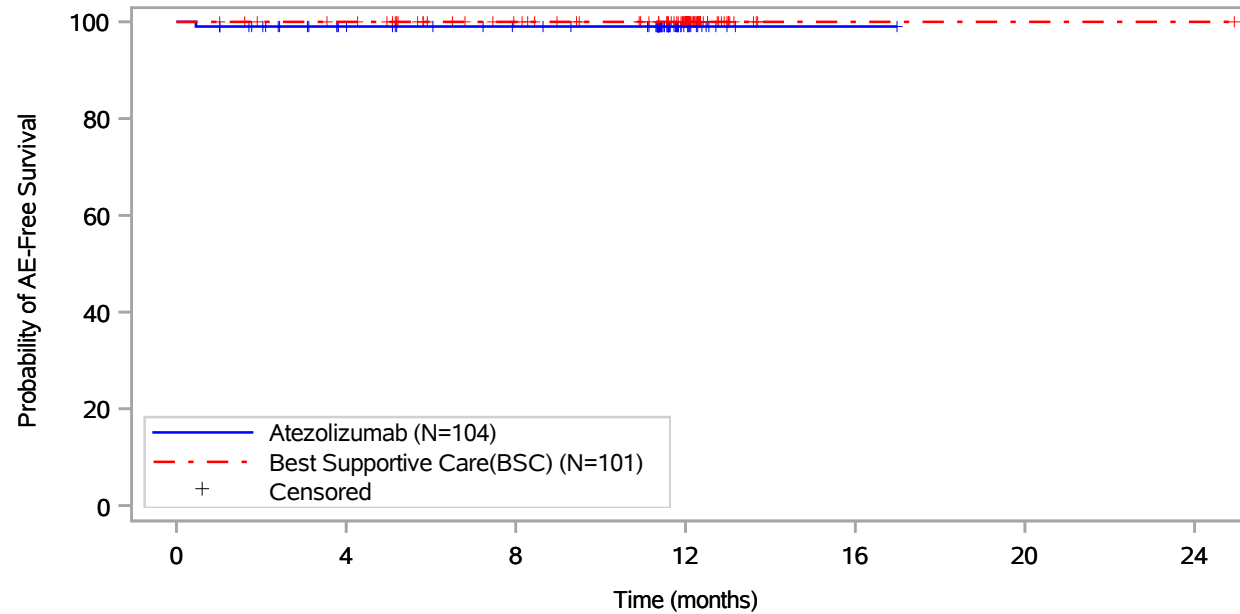
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Leukopenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

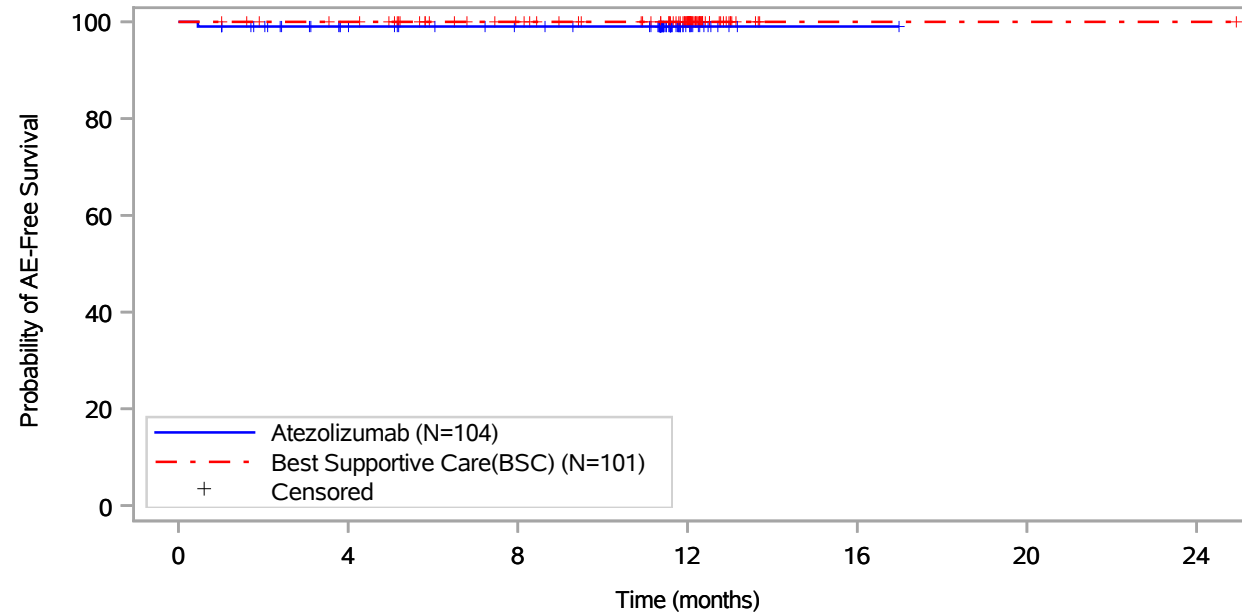
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Neutropenia



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

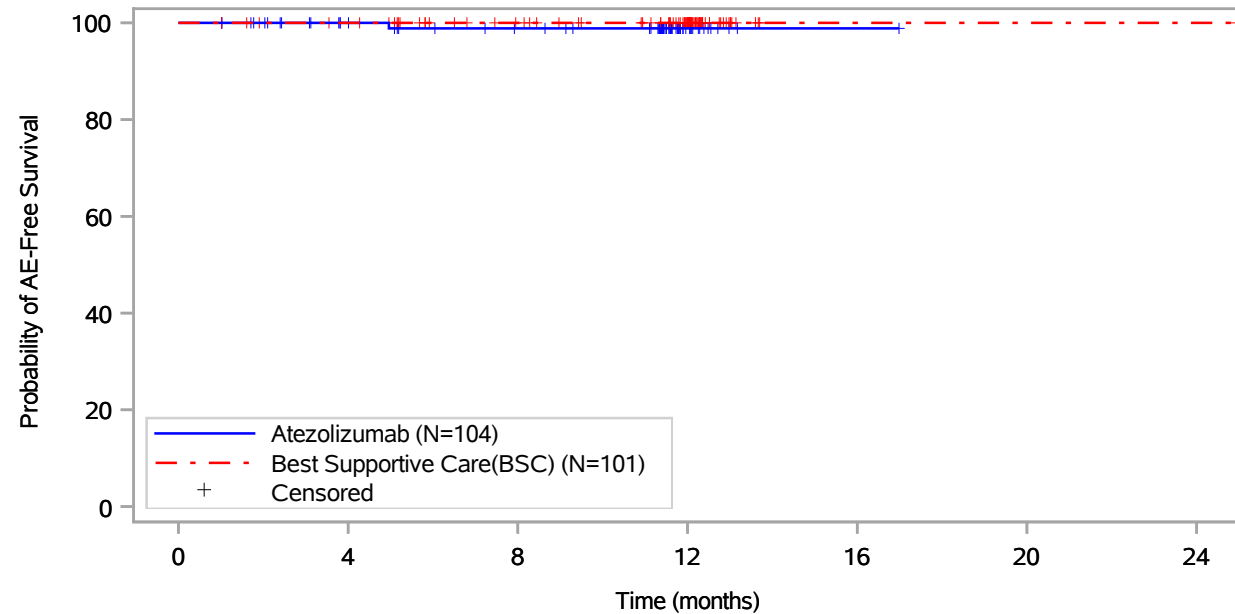
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Thrombocytopenia



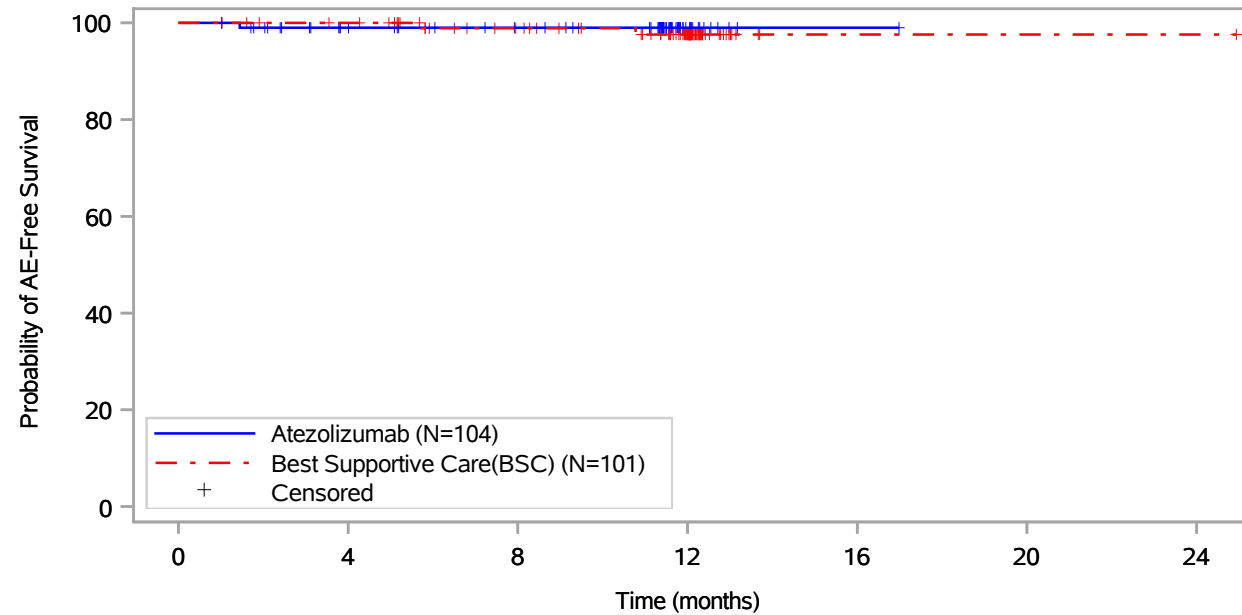
Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Eye disorders, All



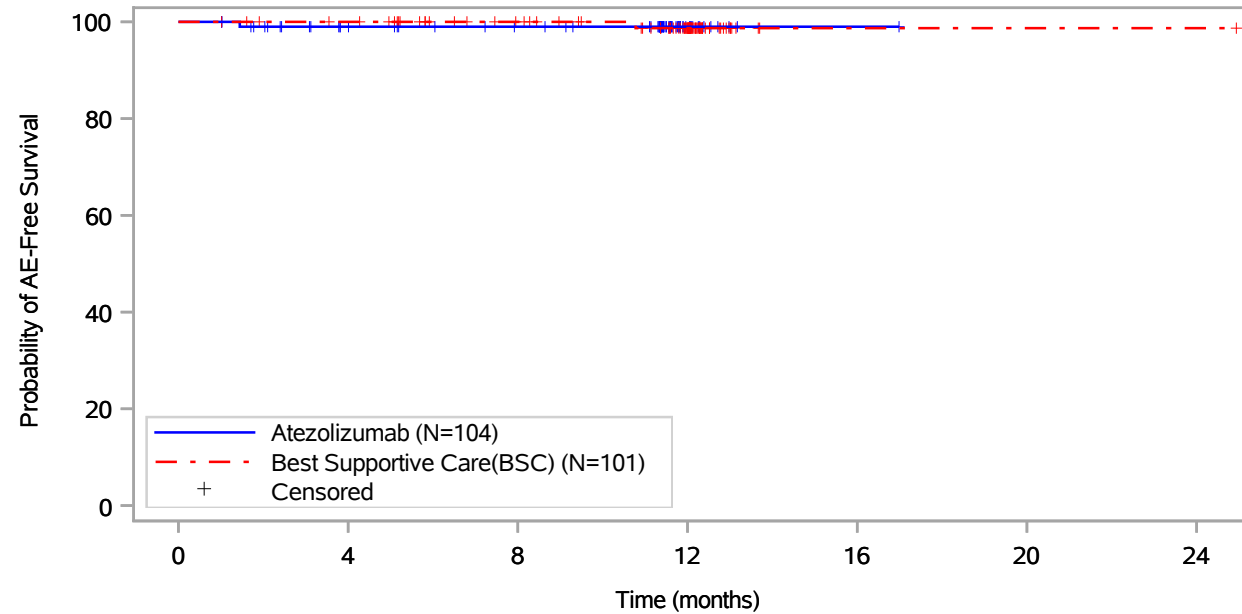
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	53	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Eye disorders, Cataract



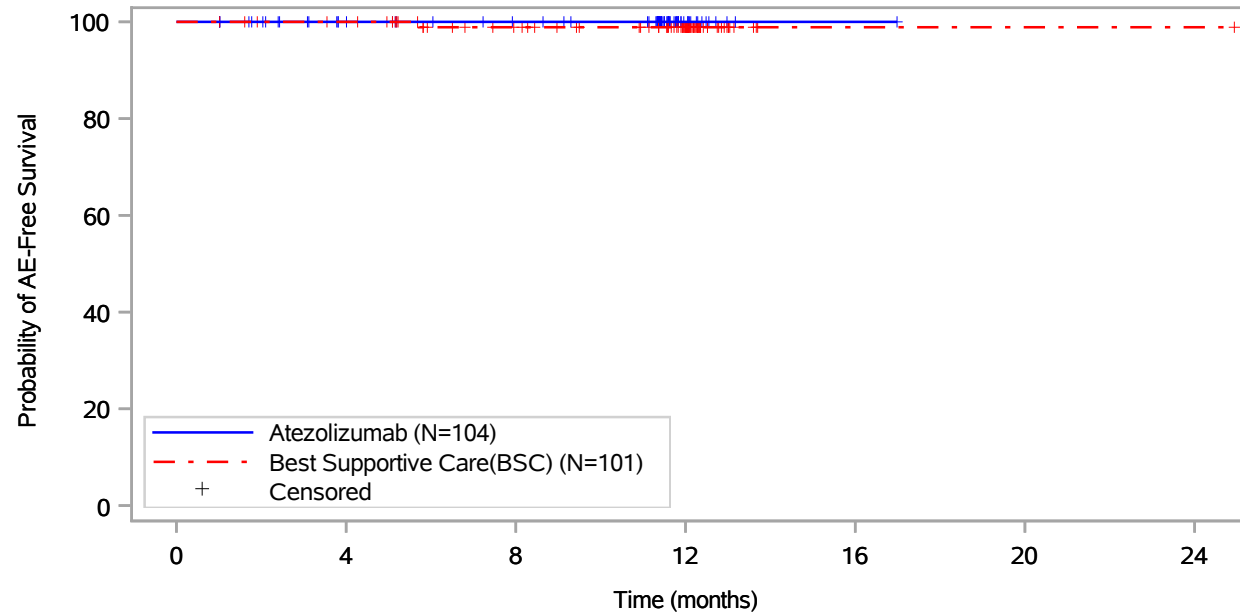
Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Eye disorders, Vitreous haemorrhage



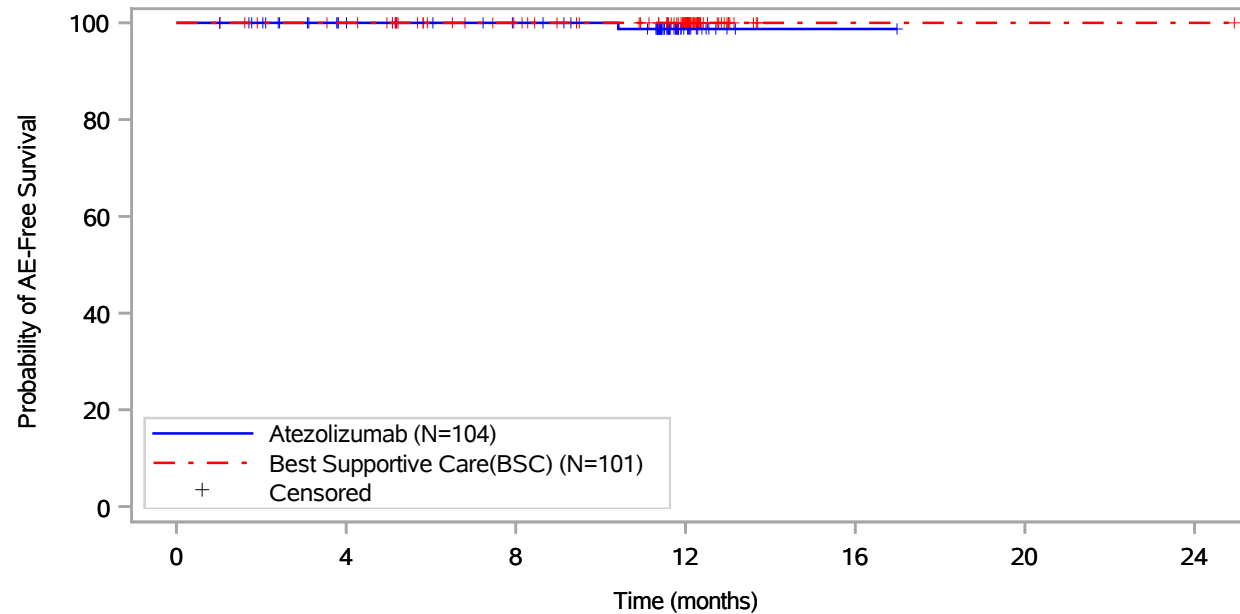
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, All



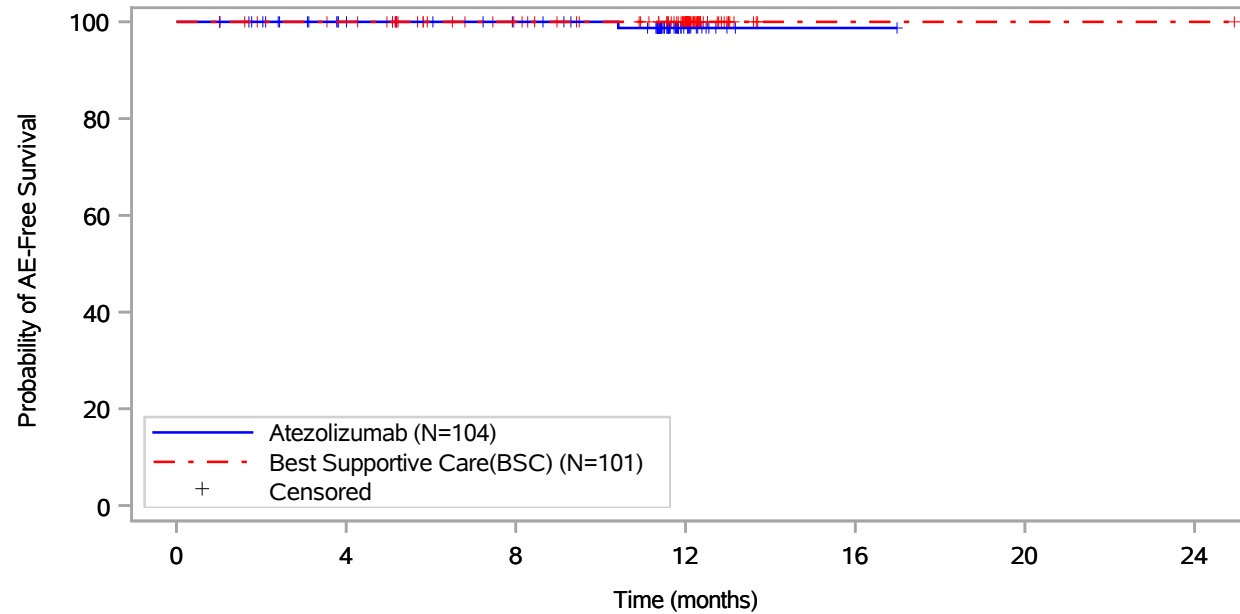
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, Colitis



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

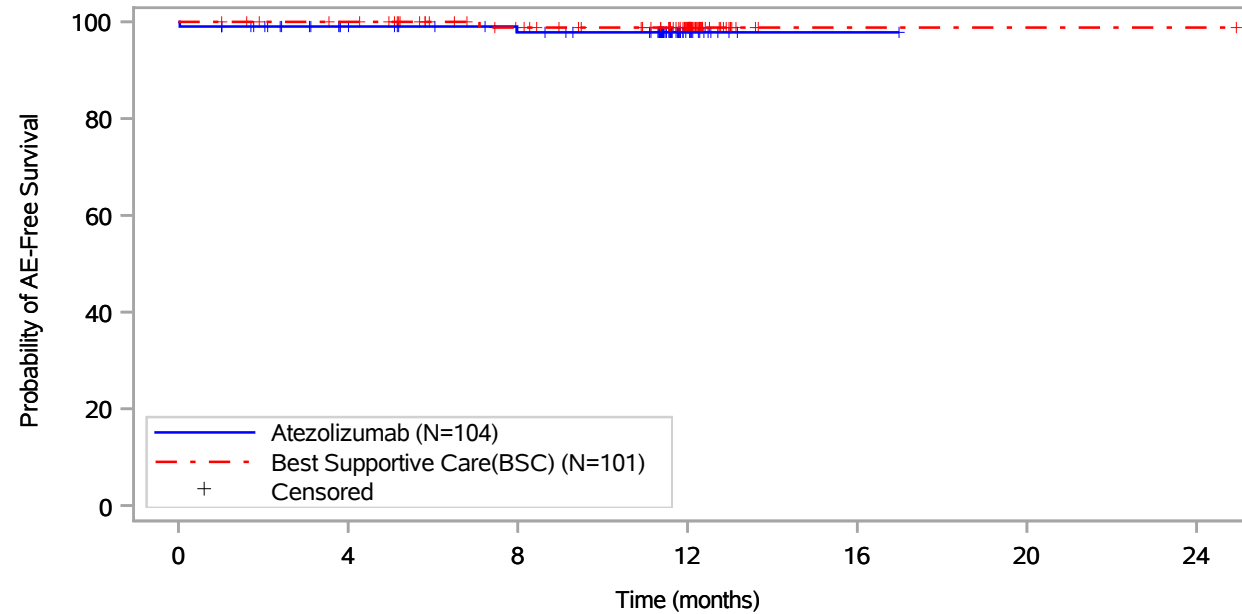
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	21	88	101	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

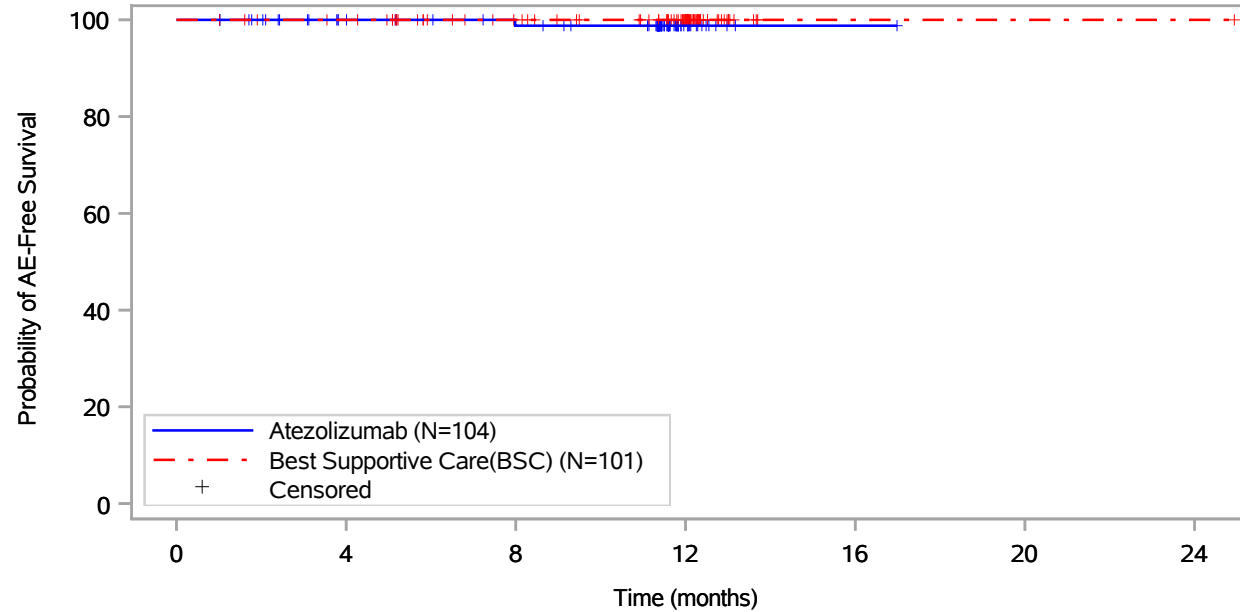
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Fatigue



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

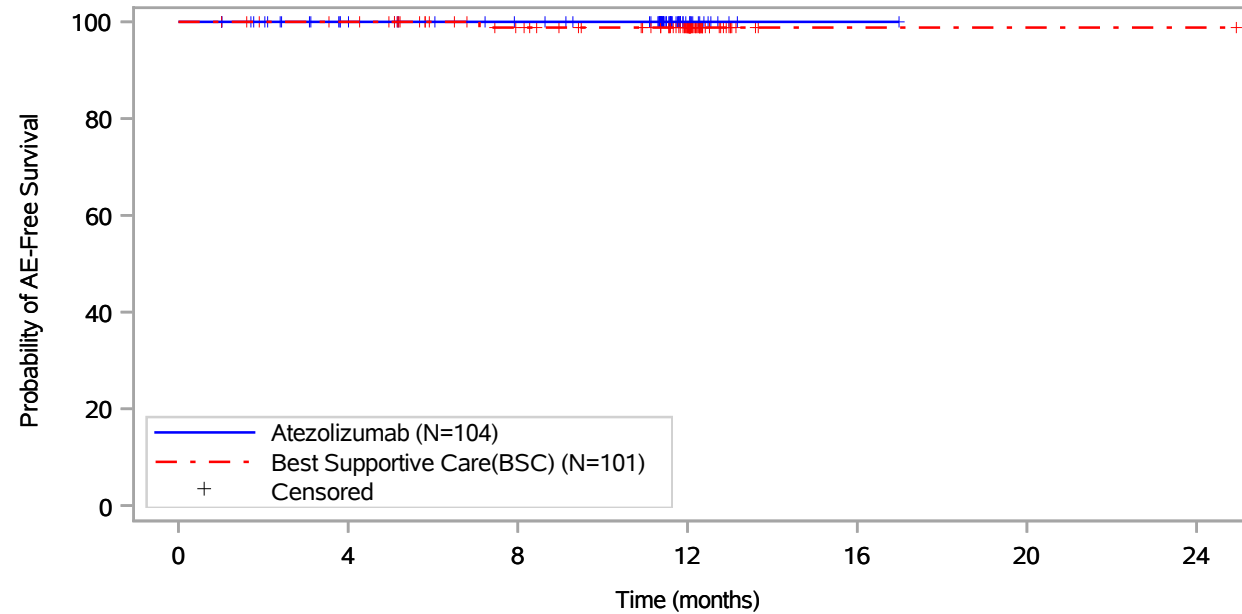
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Influenza like illness



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

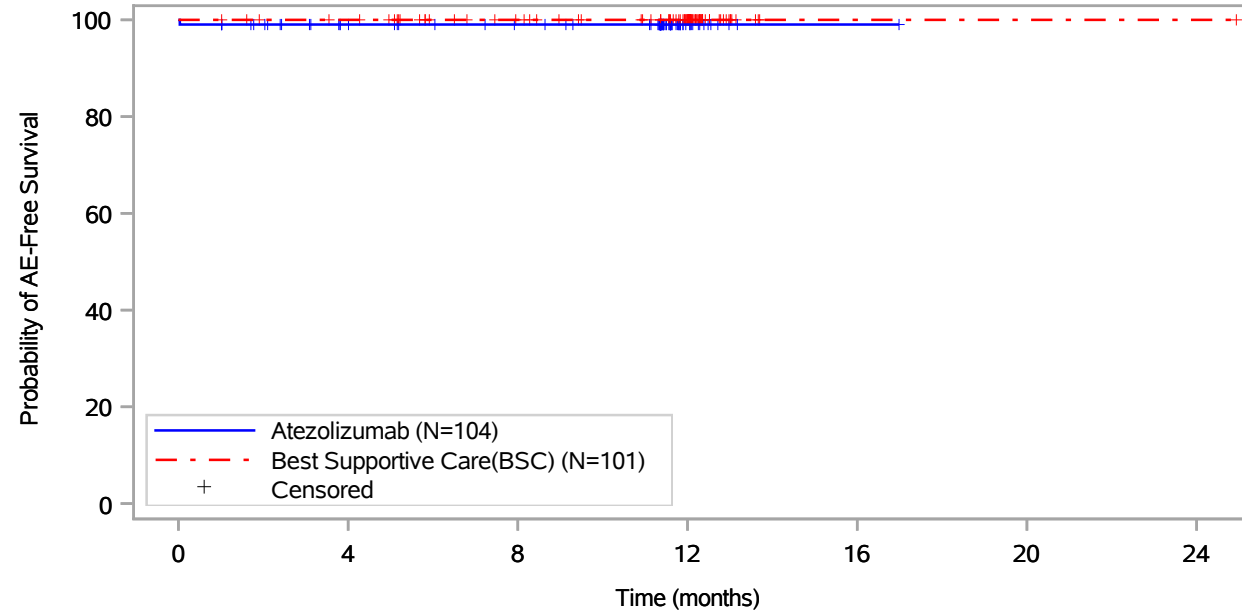
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pyrexia



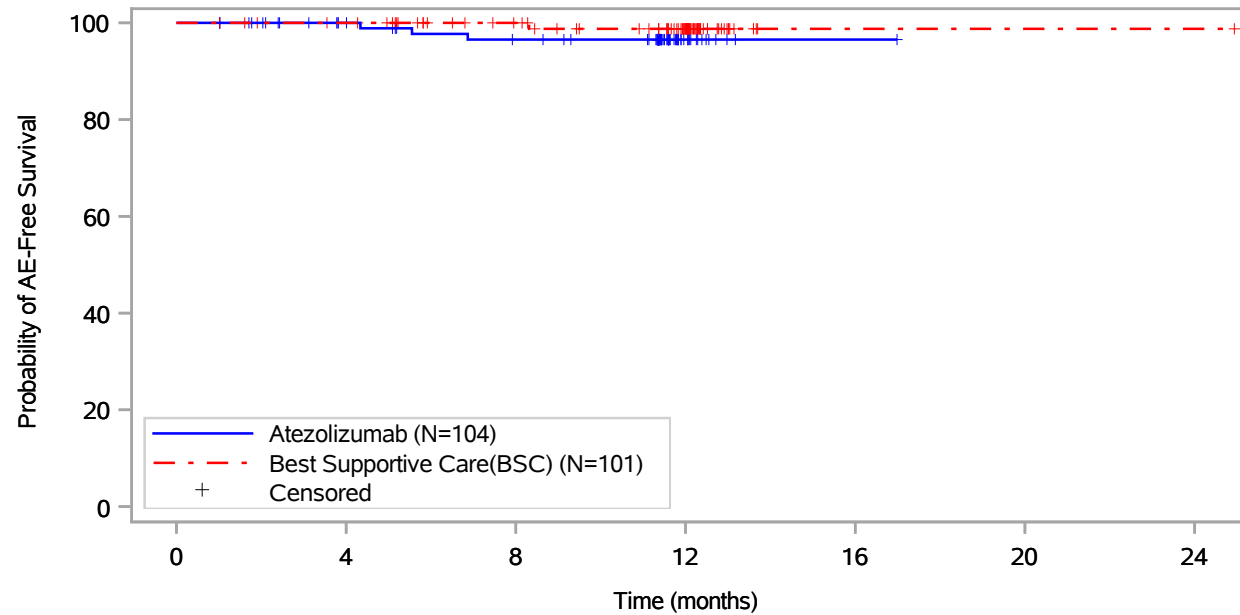
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, All



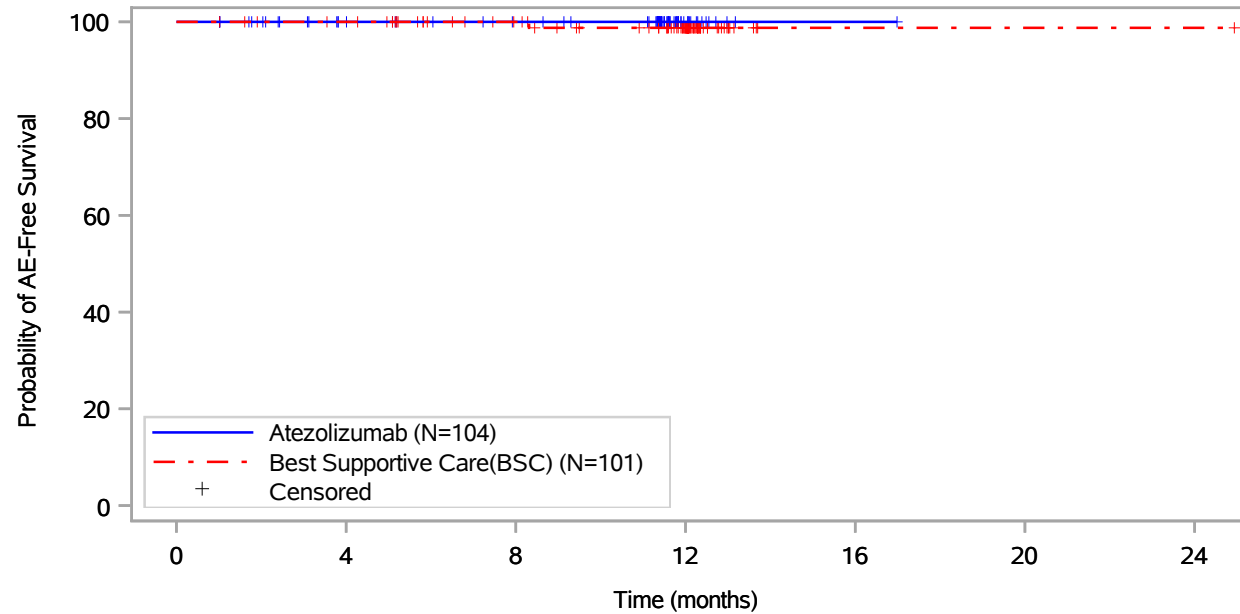
Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Cholestasis



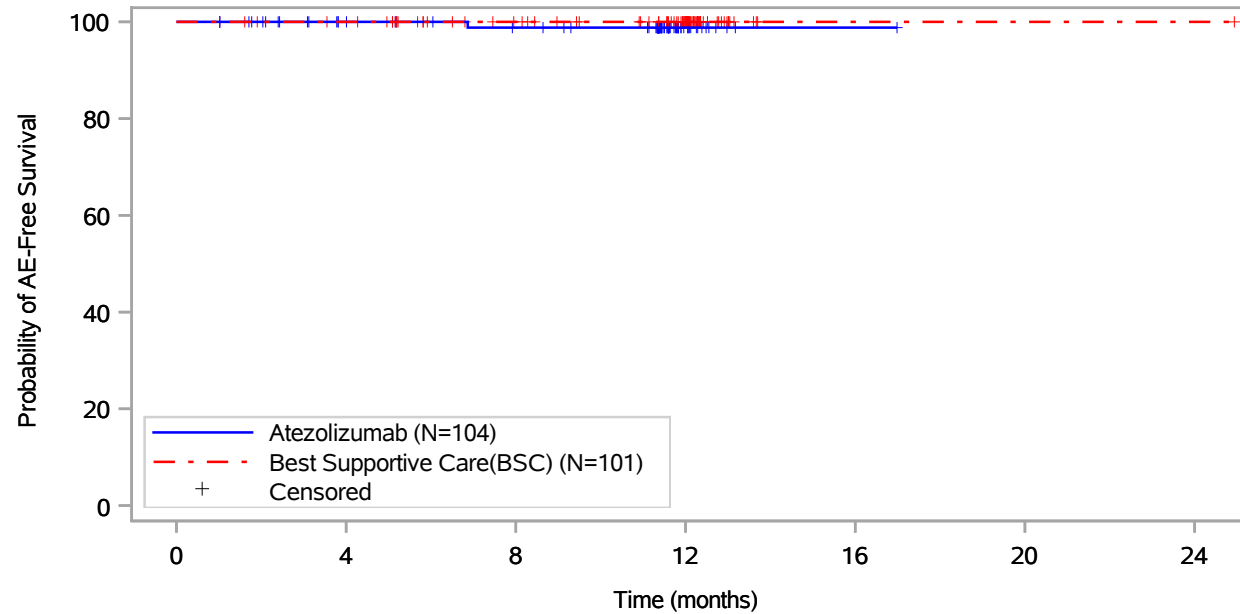
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Drug-induced liver injury



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

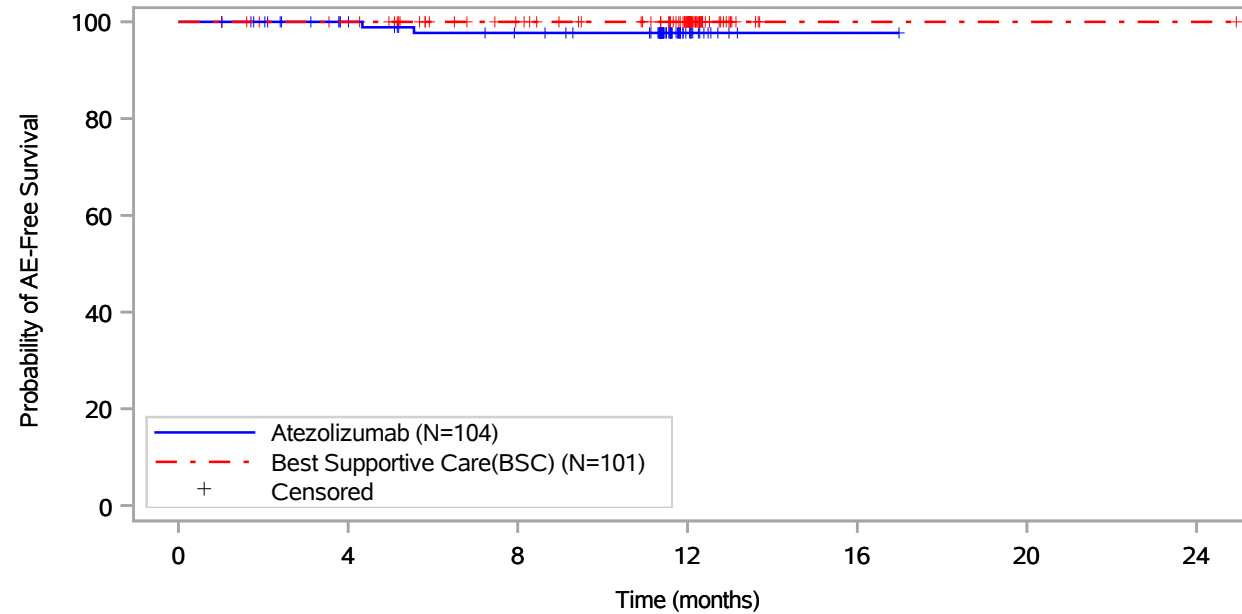
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Hepatobiliary disorders, Hepatic function abnormal



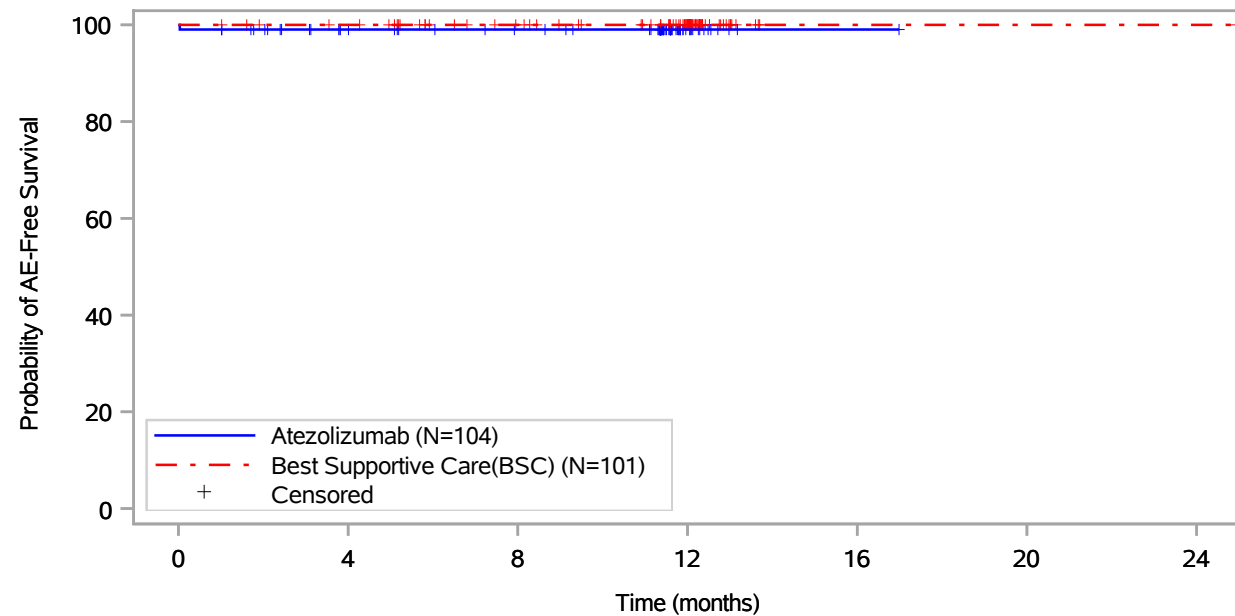
Patients at risk							
Atezolizumab (N=104)	104	90	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Immune system disorders, All



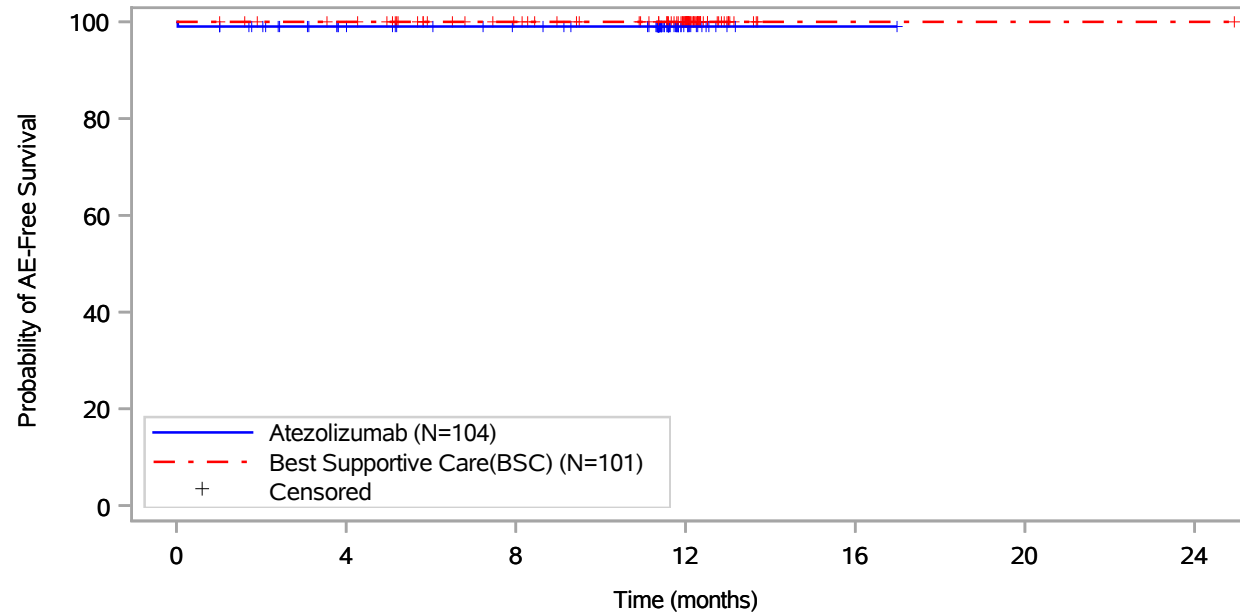
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Immune system disorders, Hypersensitivity



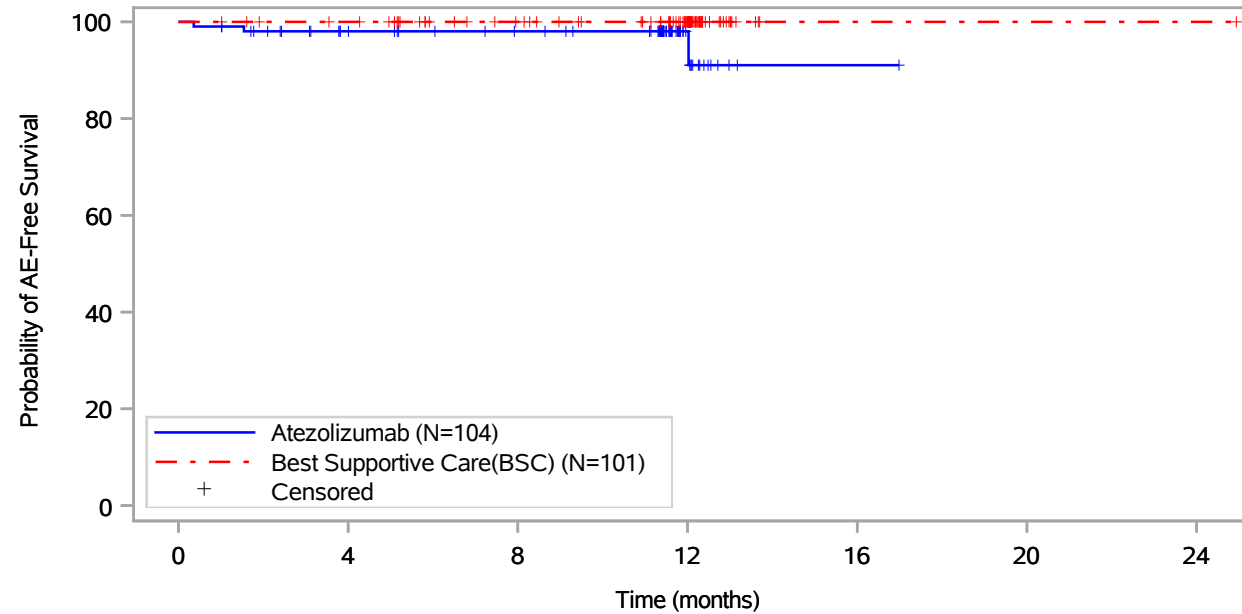
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Infections and infestations, All



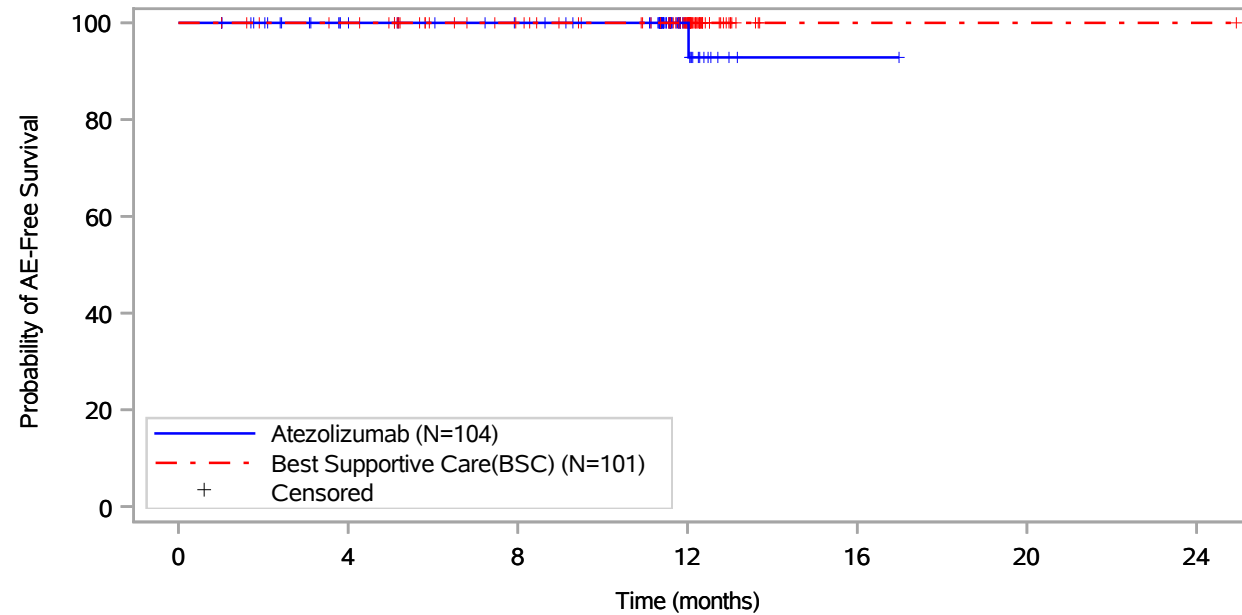
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	13	20	88	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Infections and infestations, Cellulitis



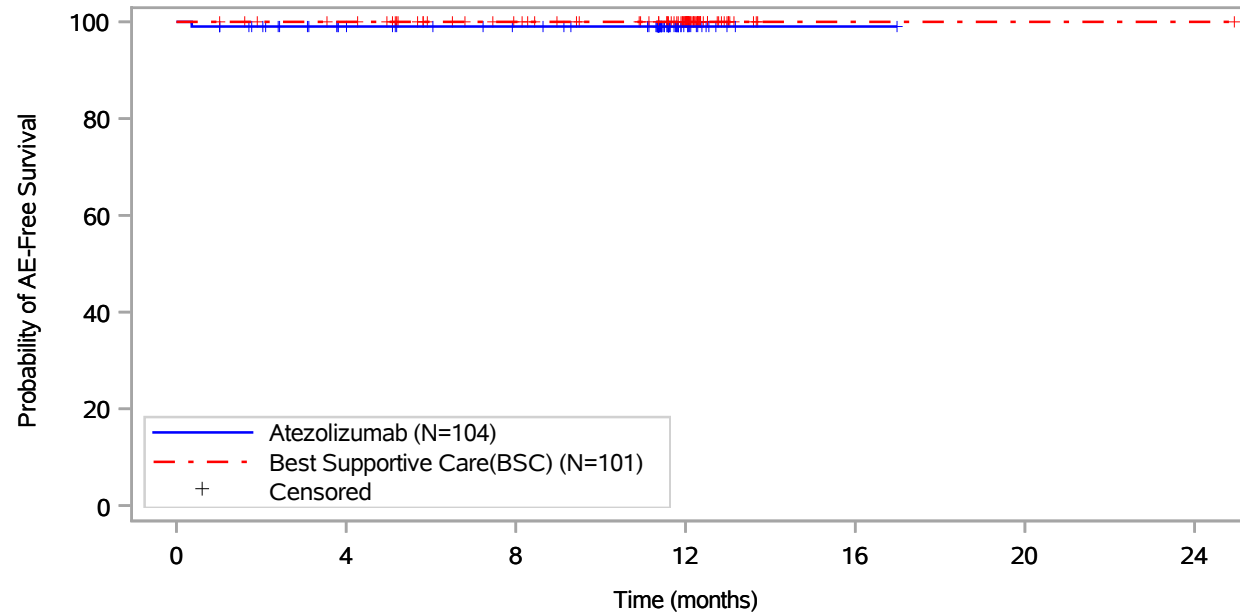
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Infections and infestations, Encephalitis



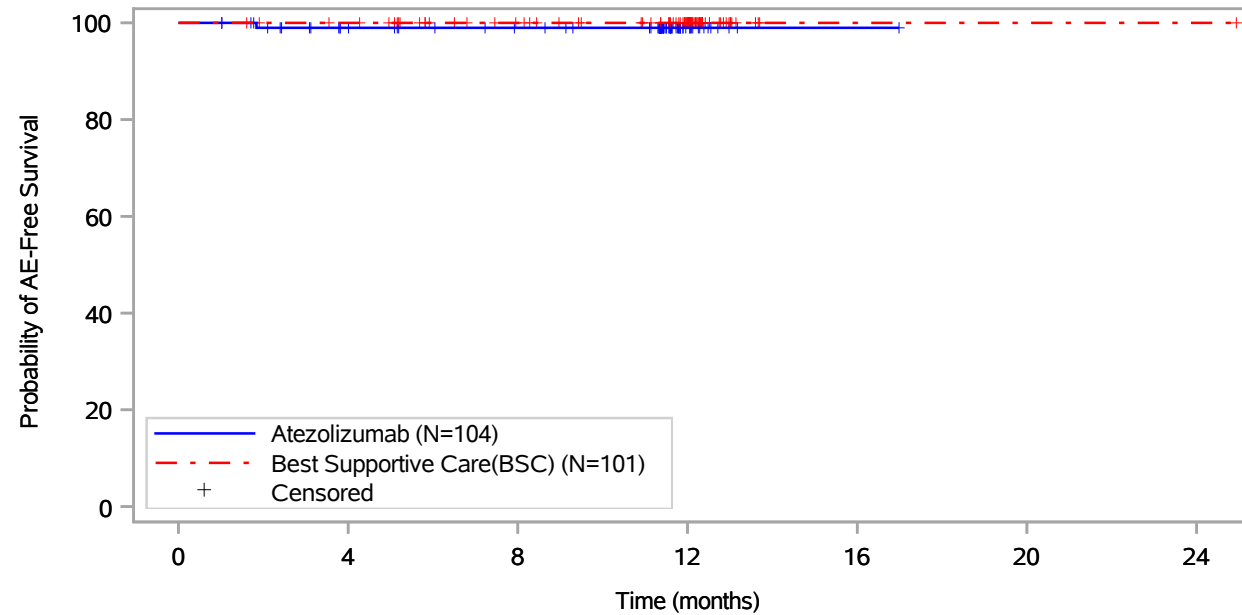
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Infections and infestations, Kidney infection



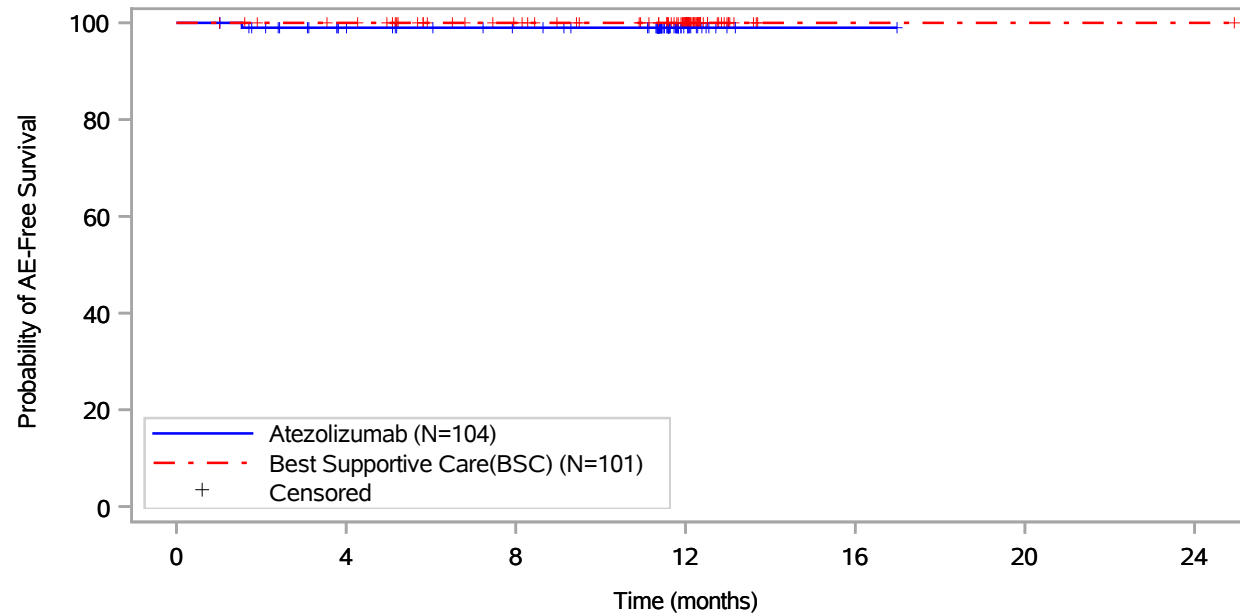
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Infections and infestations, Meningitis



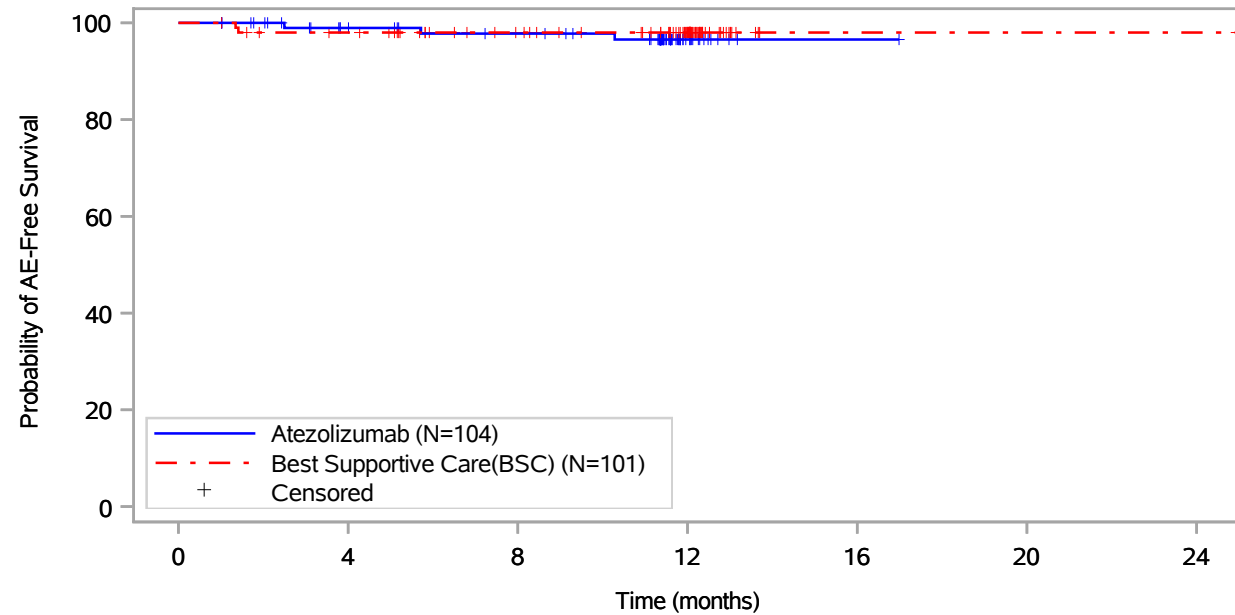
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Investigations, All



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	95	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	19	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98

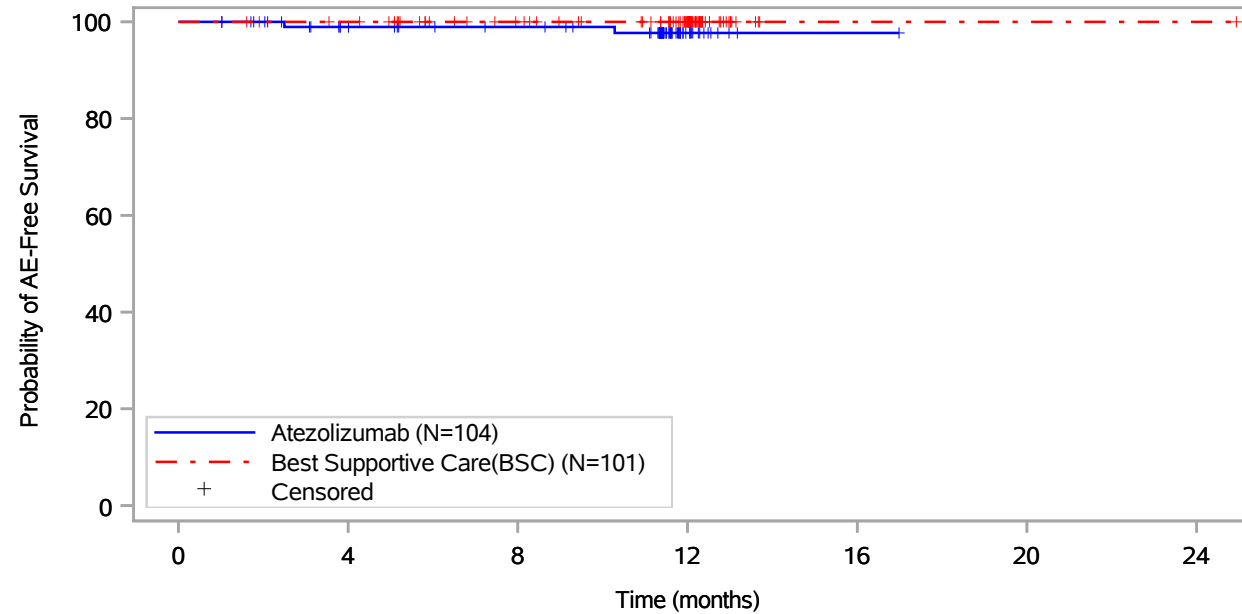
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Investigations, Alanine aminotransferase increased



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	20	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

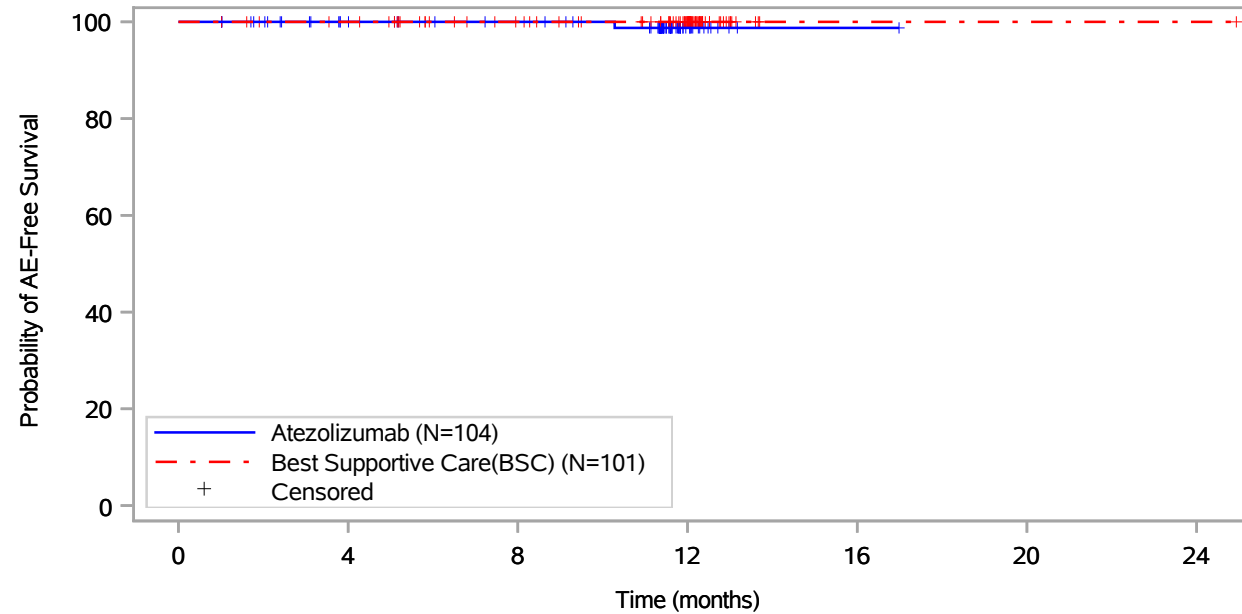
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Investigations, Aspartate aminotransferase increased



Patients at risk							
Atezolizumab (N=104)	104	89	83	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

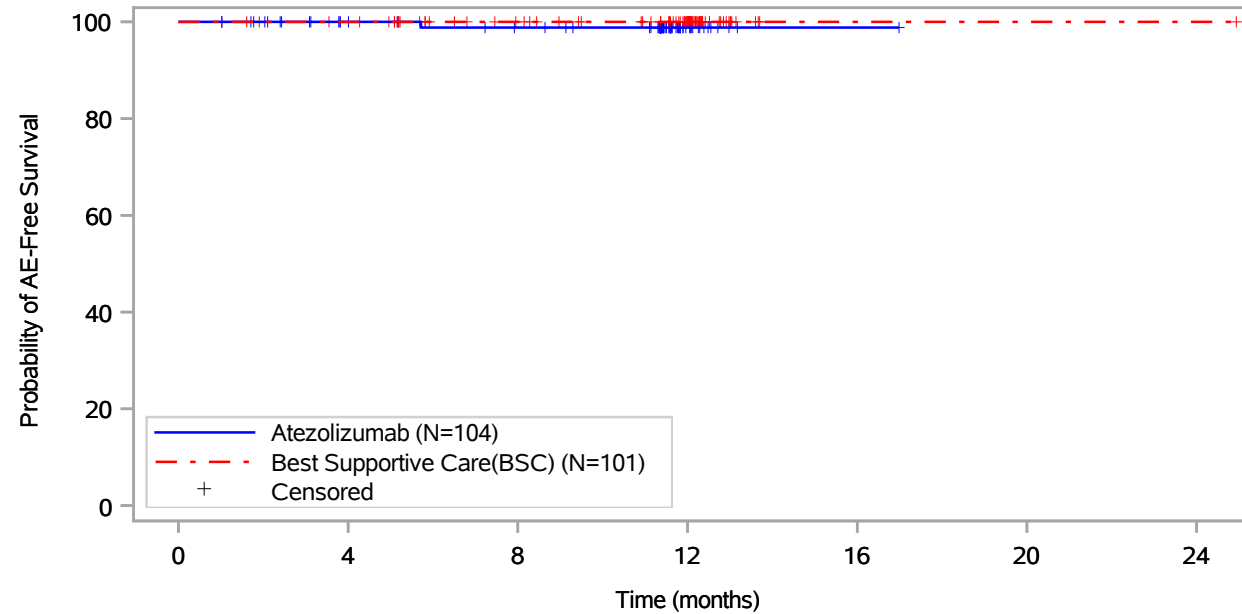
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Investigations, Gamma-glutamyltransferase increased



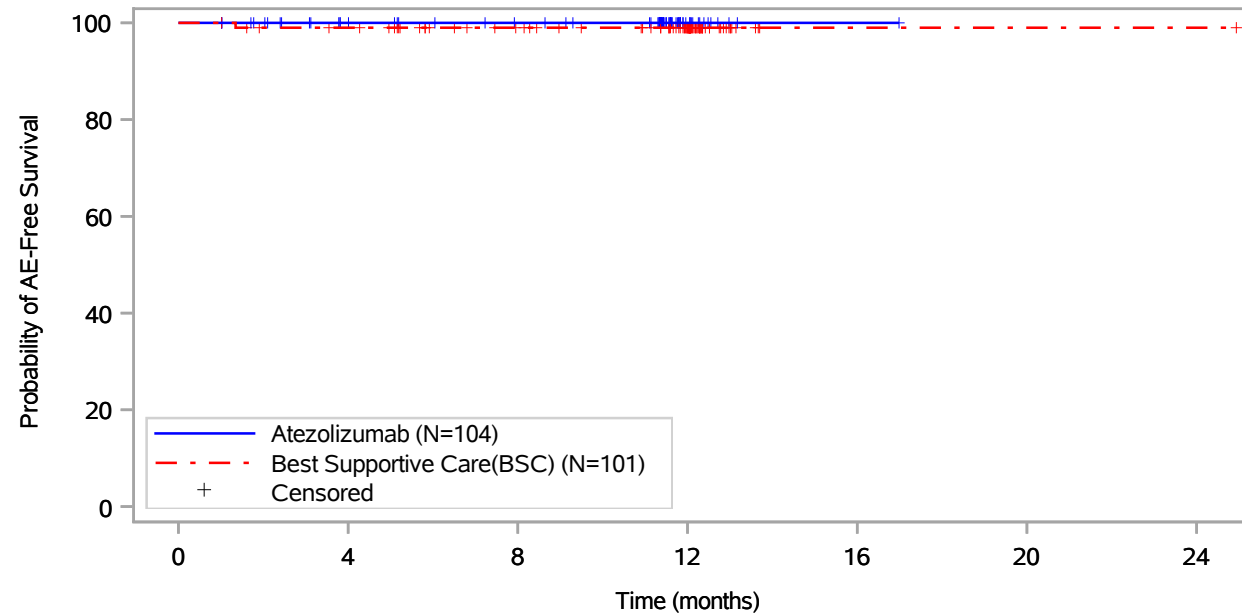
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Investigations, Neutrophil count decreased



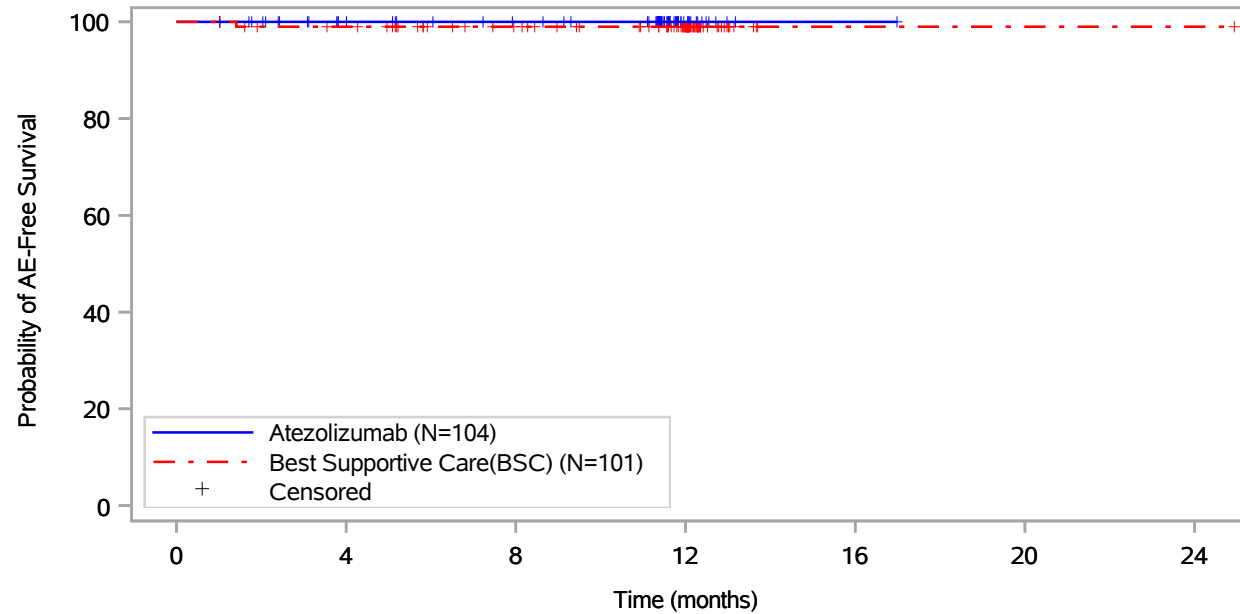
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Investigations, Weight increased



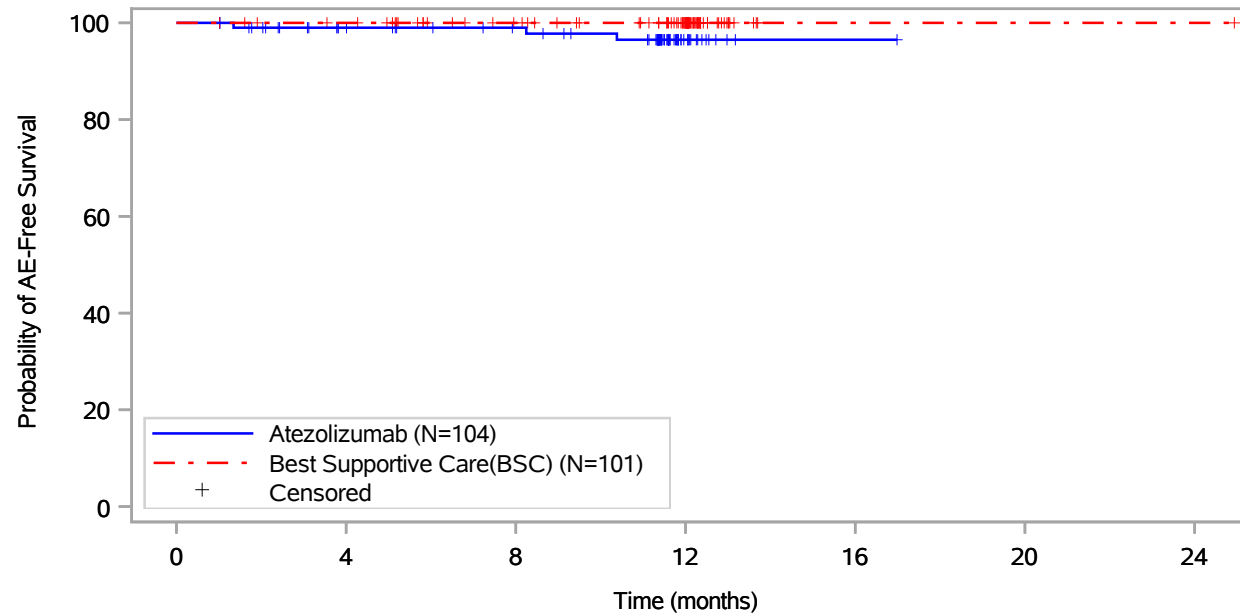
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Metabolism and nutrition disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	87	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

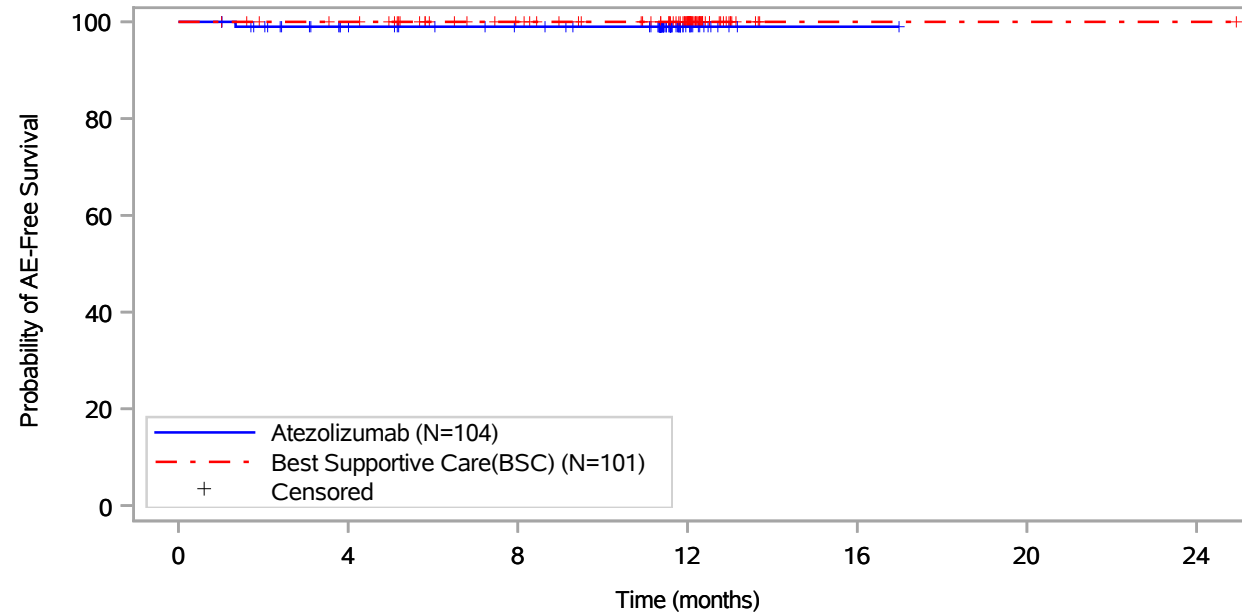
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hyperkalaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	88	81	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

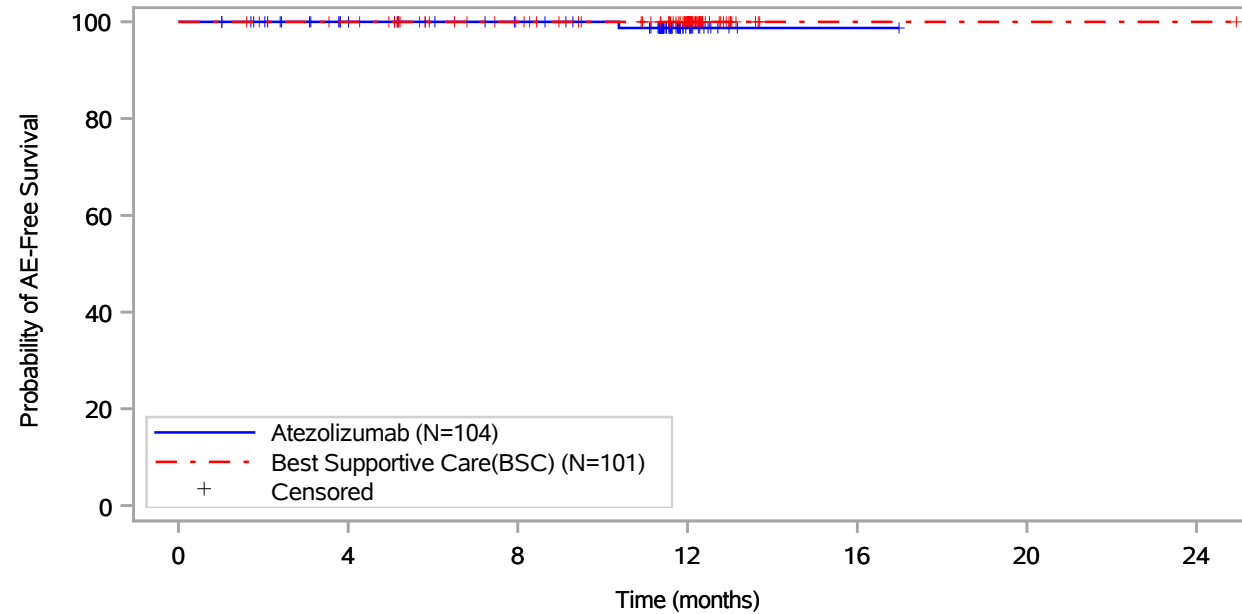
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypocalcaemia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	89	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

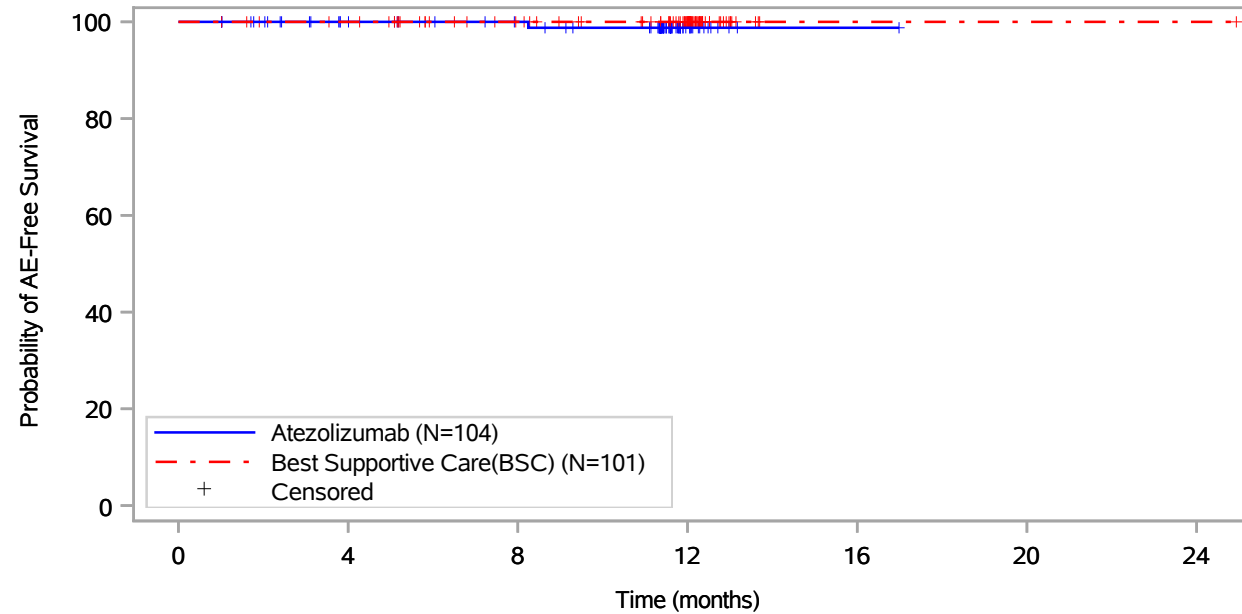
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypophosphataemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

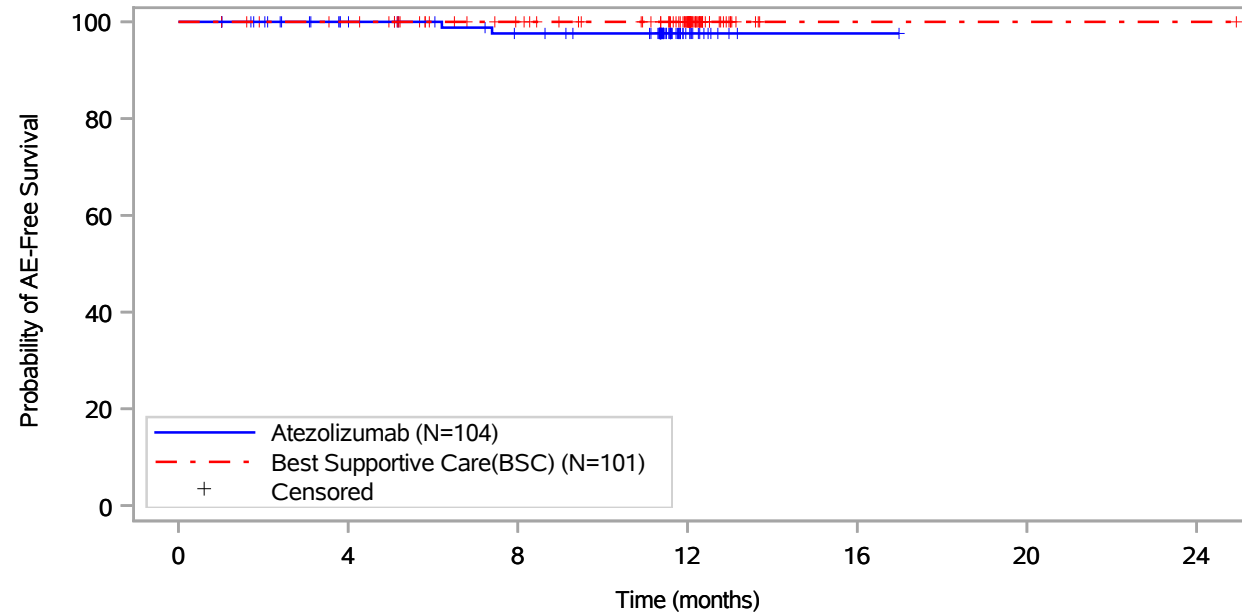
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	80	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

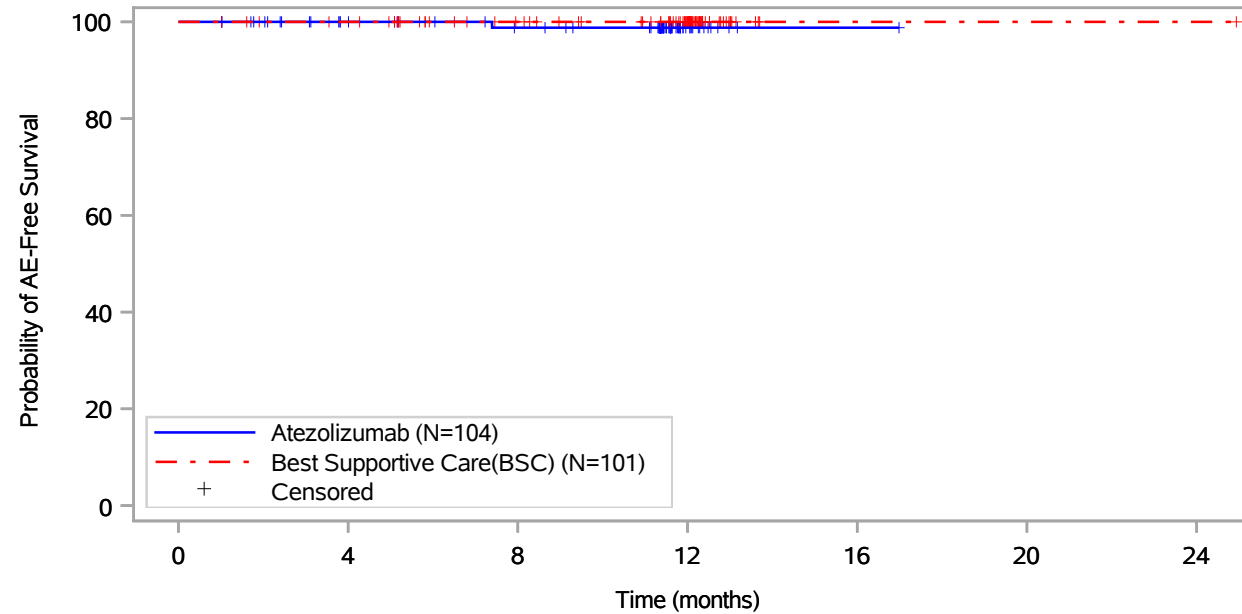
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Muscular weakness



Patients at risk							
Atezolizumab (N=104)	104	89	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

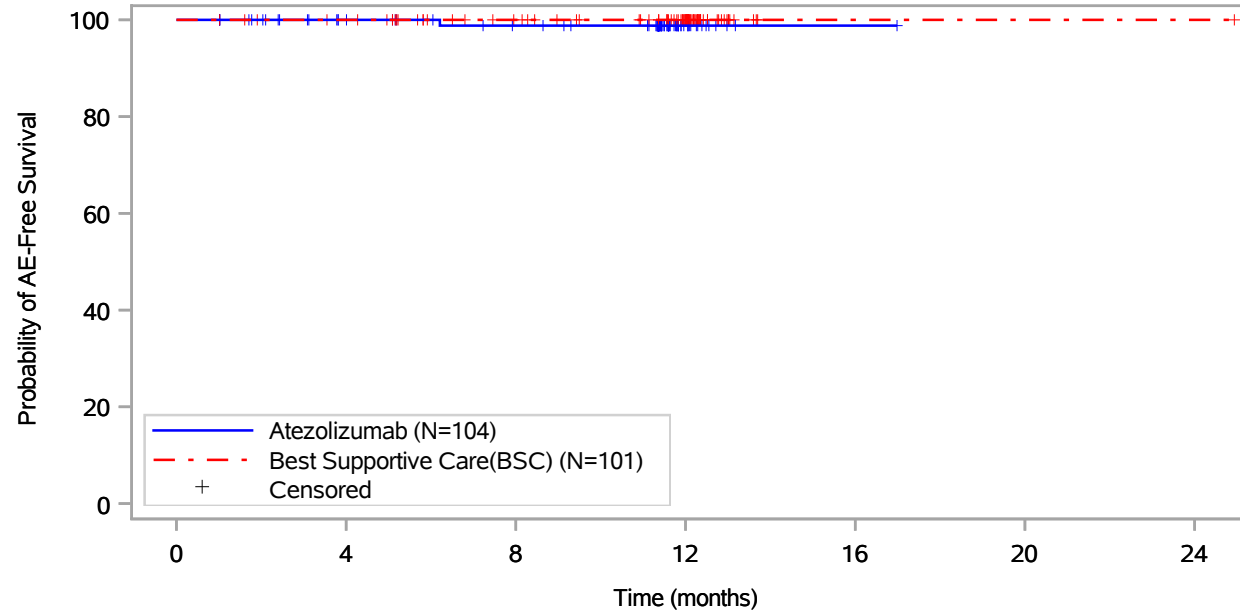
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Musculoskeletal and connective tissue disorders, Myalgia



Patients at risk							
Atezolizumab (N=104)	104	89	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

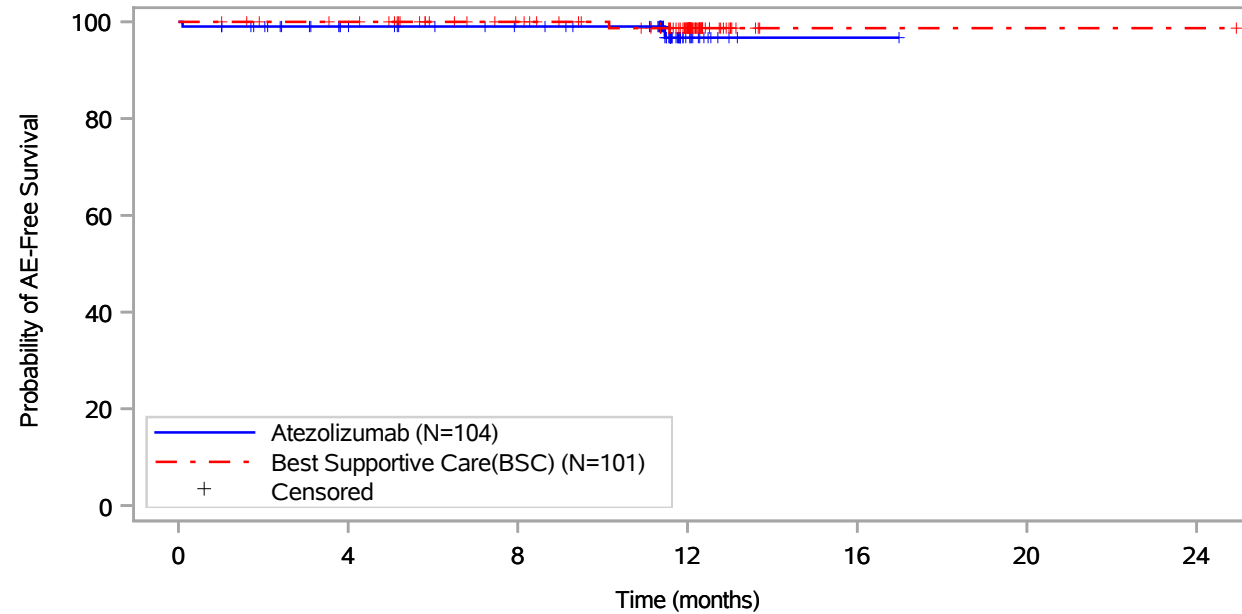
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

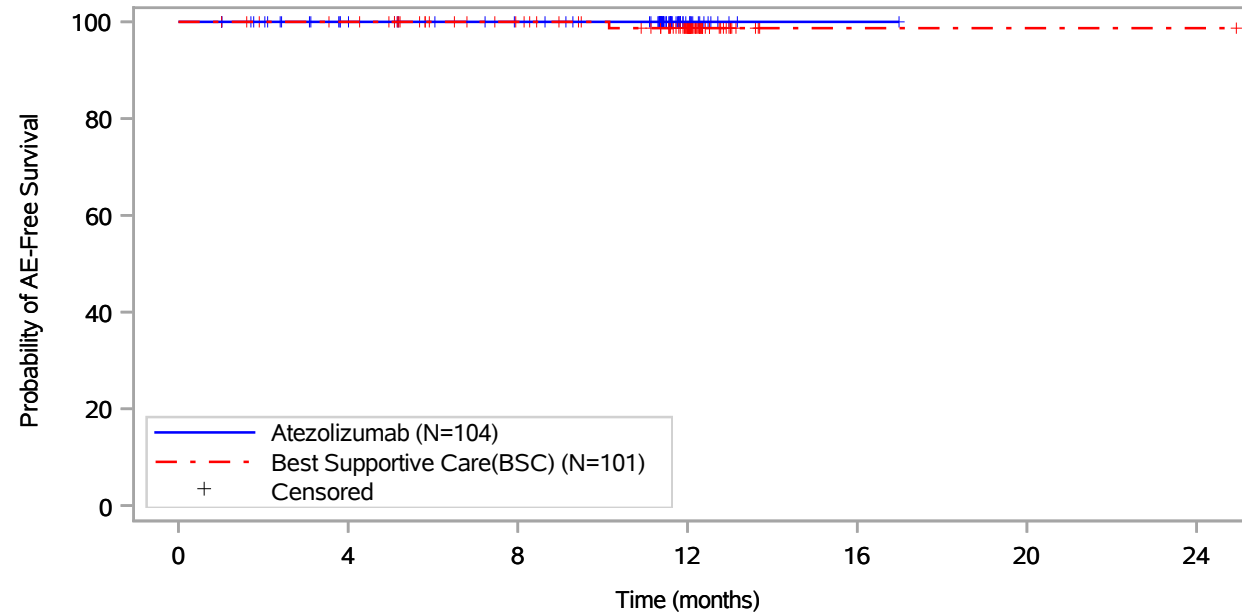
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

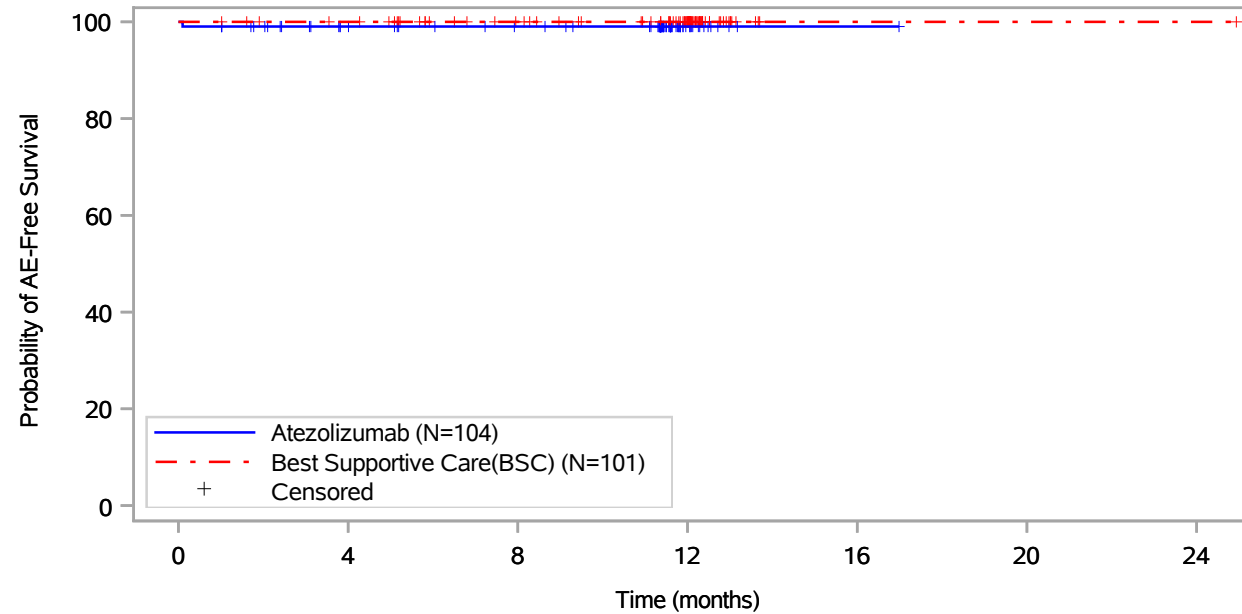
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Renal neoplasm



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

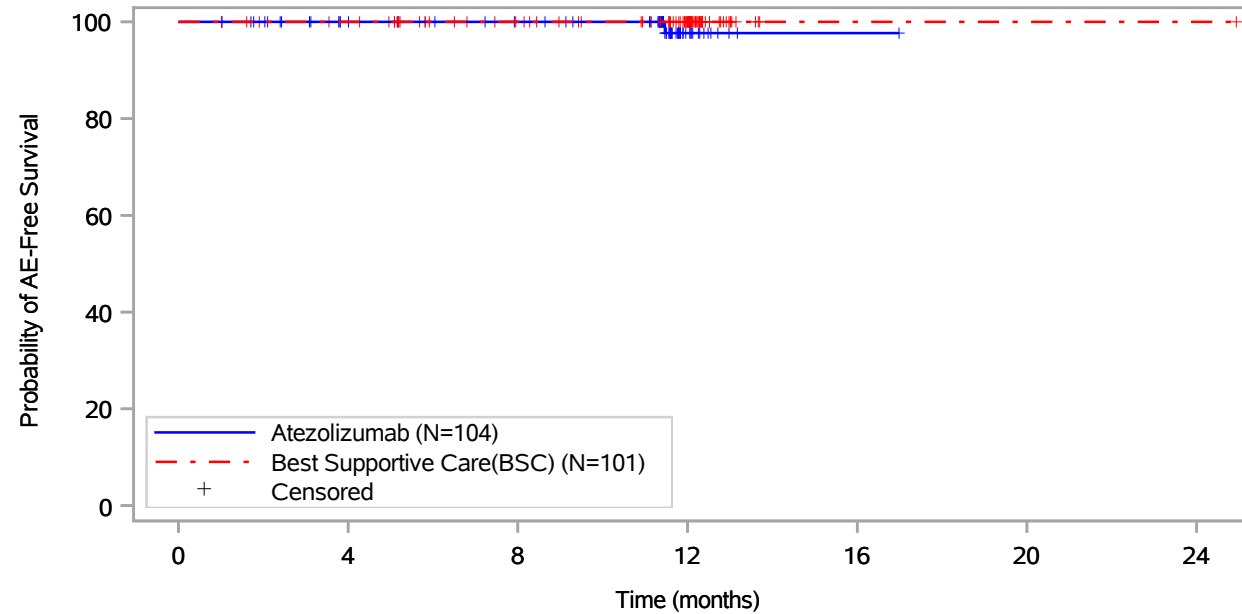
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



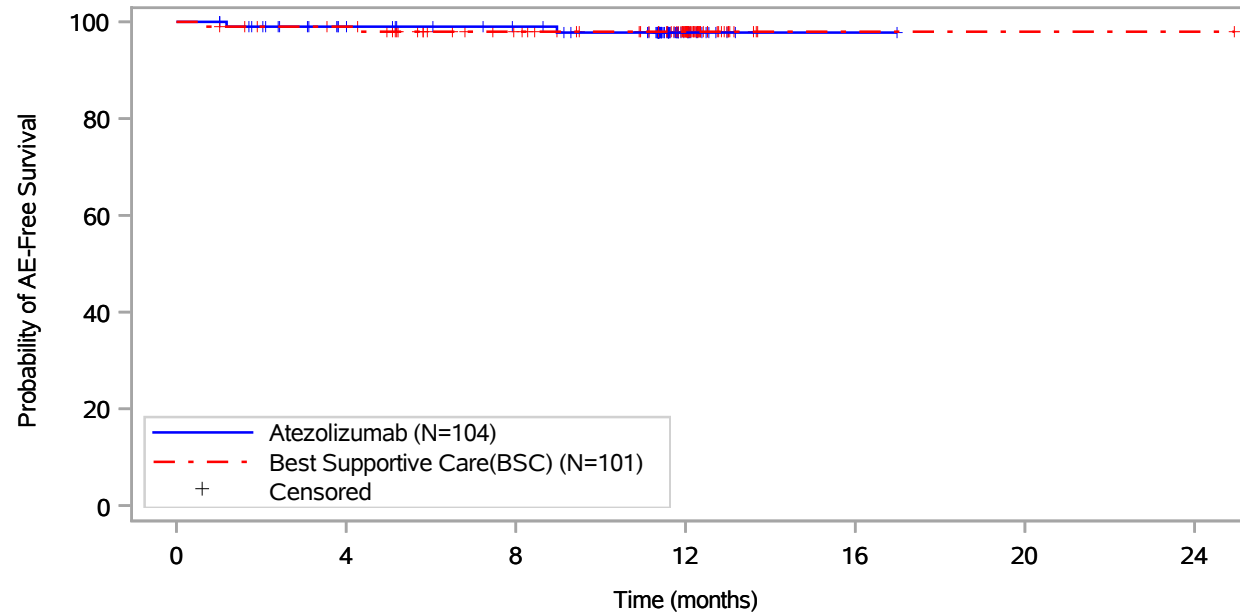
Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Nervous system disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	81	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	88	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	98	98	98

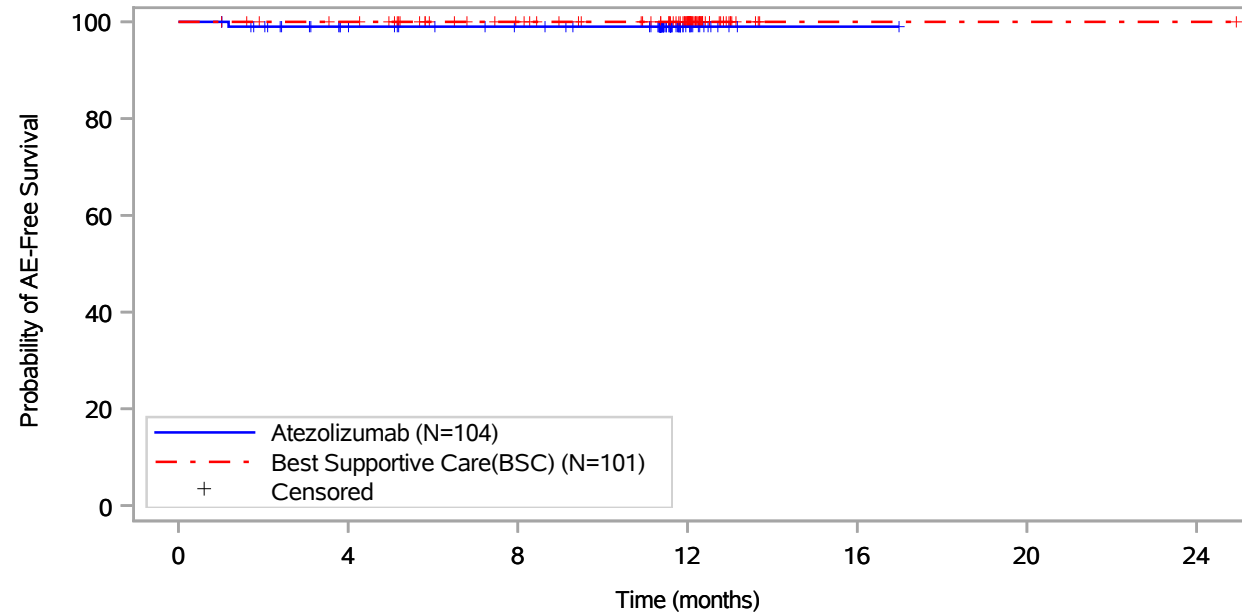
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



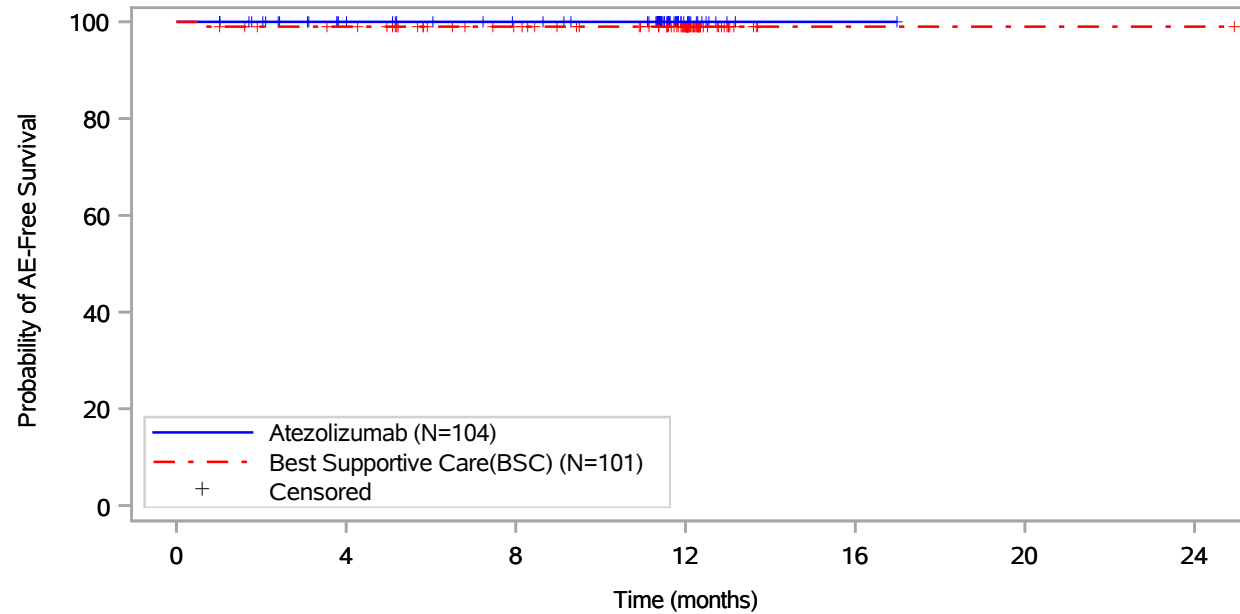
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Nervous system disorders, Paraesthesia



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

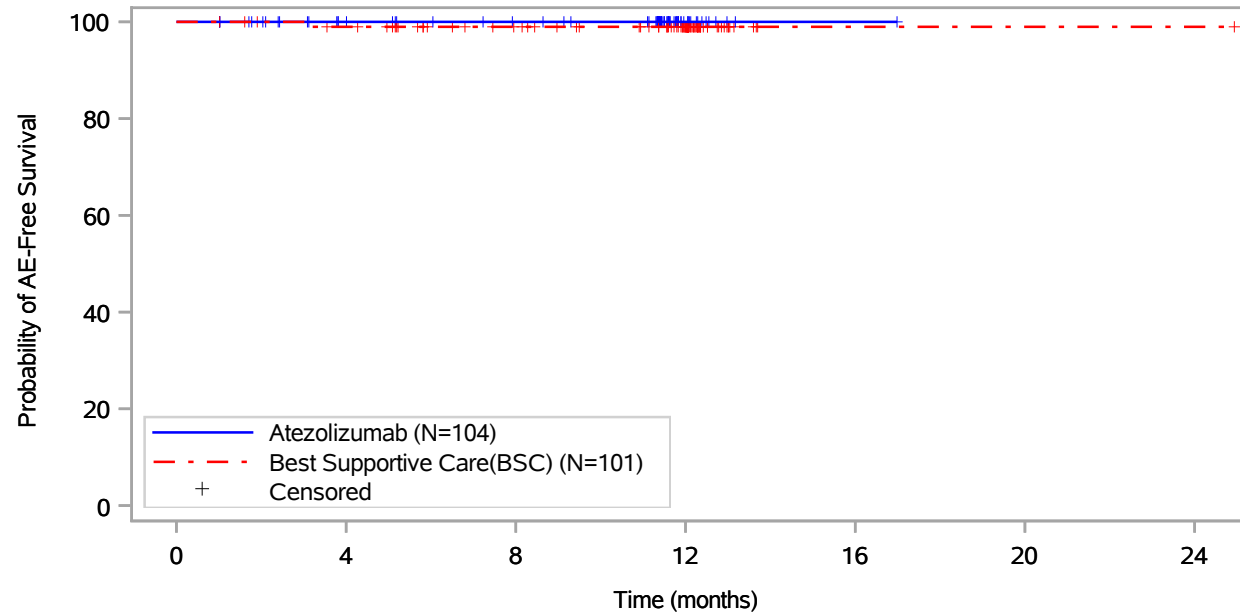
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 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

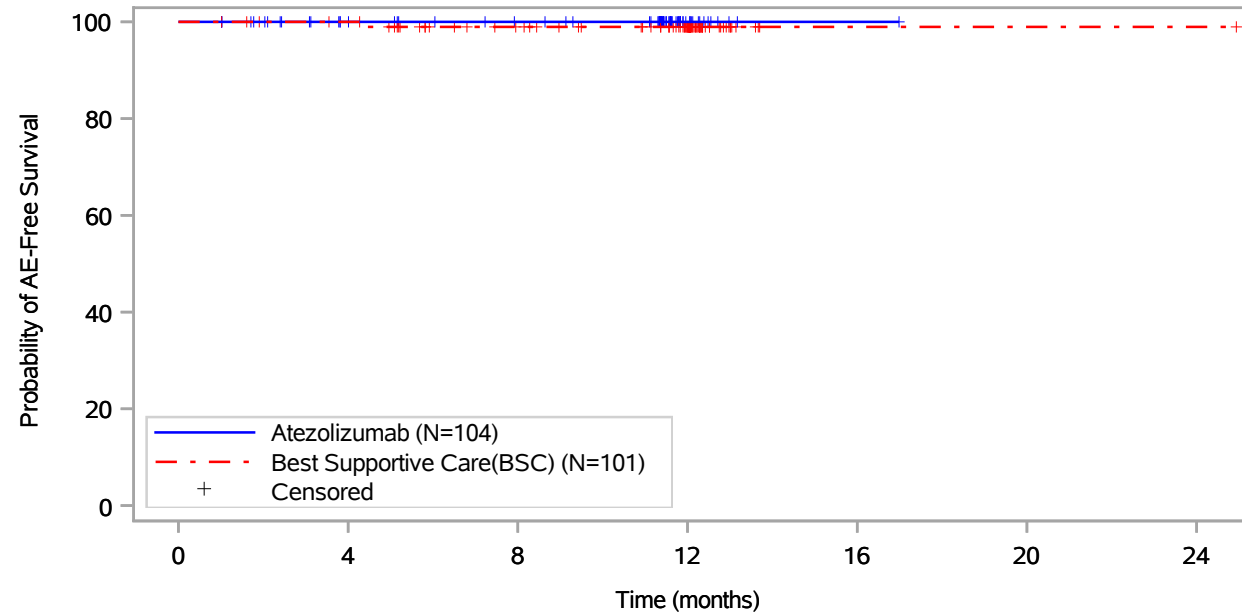
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Nervous system disorders, Post herpetic neuralgia



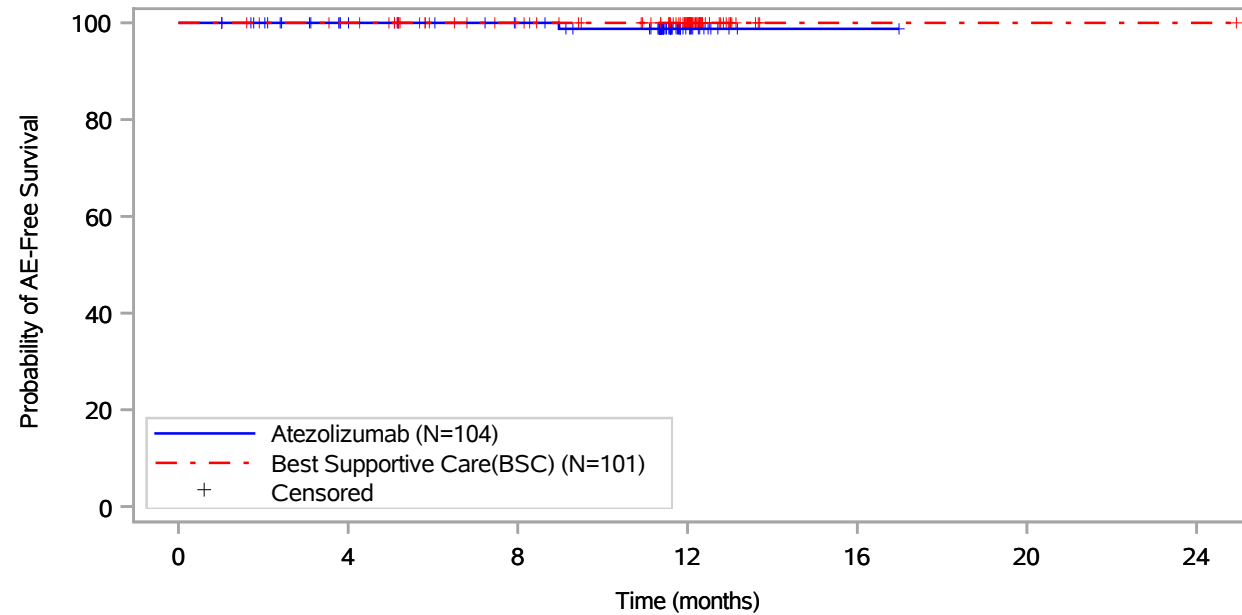
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Nervous system disorders, Syncope



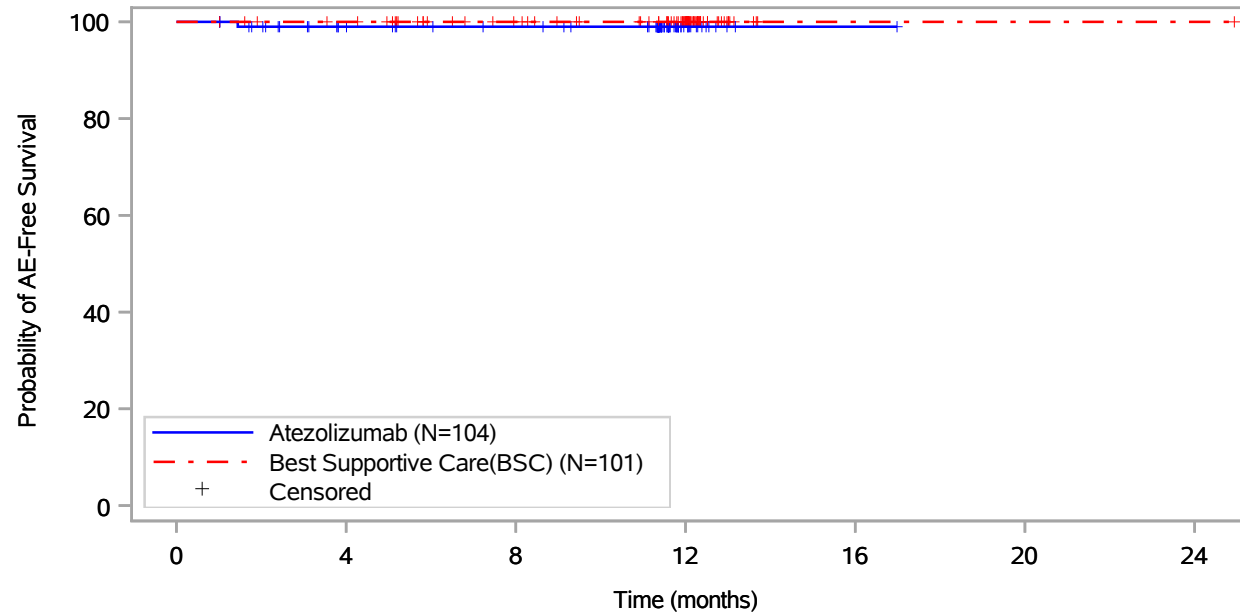
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Renal and urinary disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

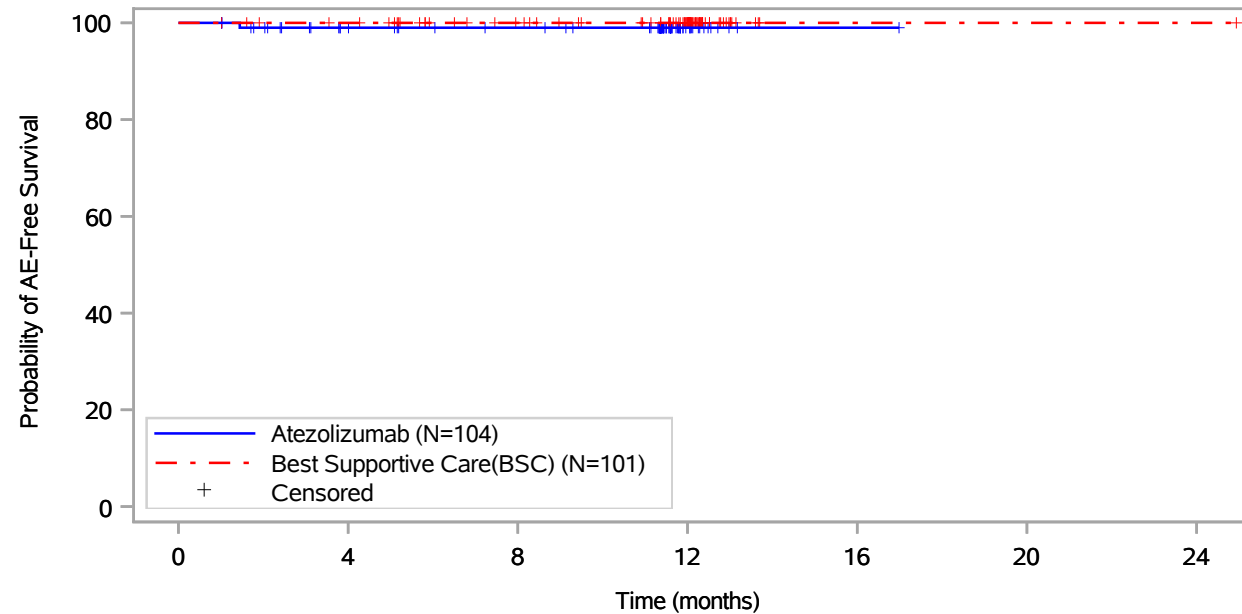
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Renal and urinary disorders, Chronic kidney disease



Patients at risk							
Atezolizumab (N=104)	104	88	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

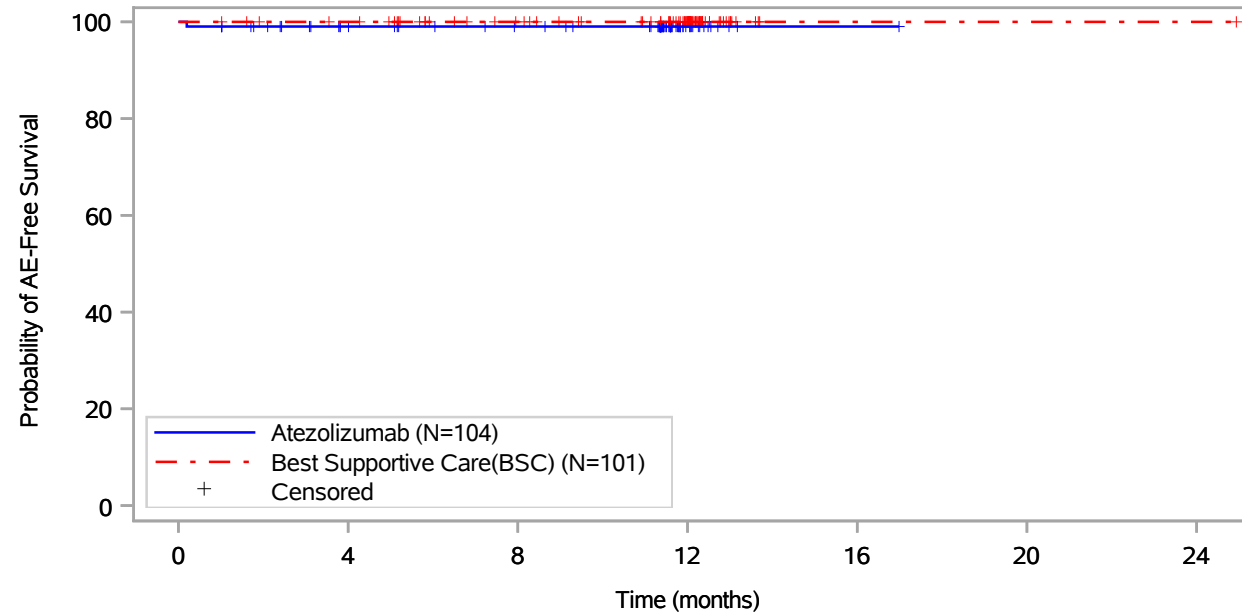
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

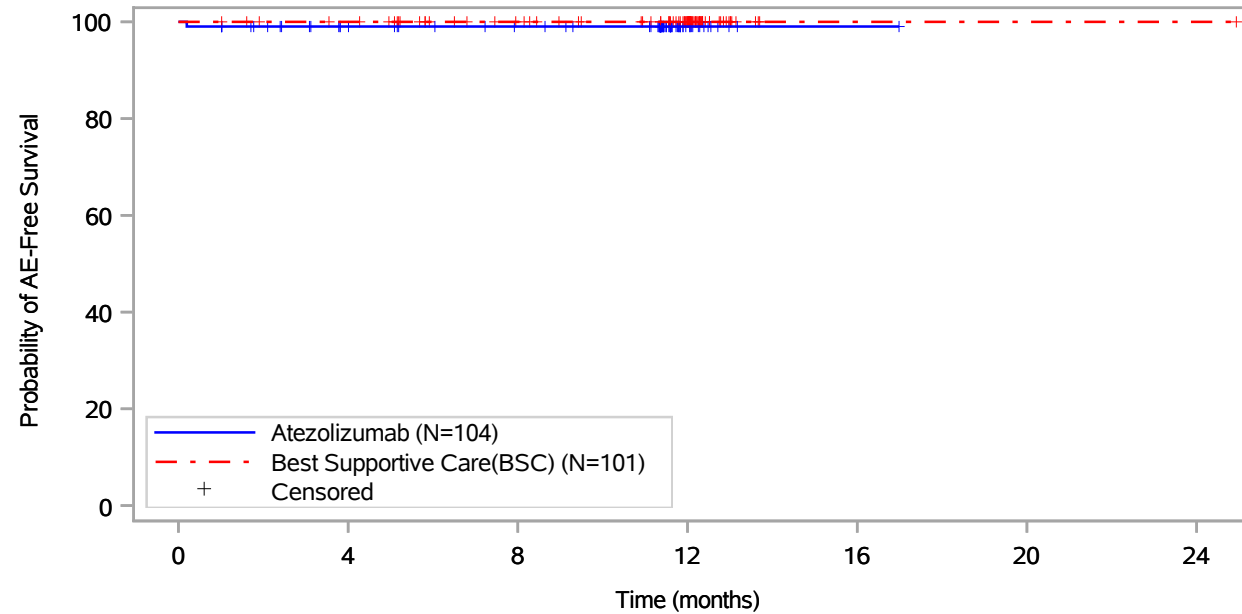
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Reproductive system and breast disorders, Genital rash



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

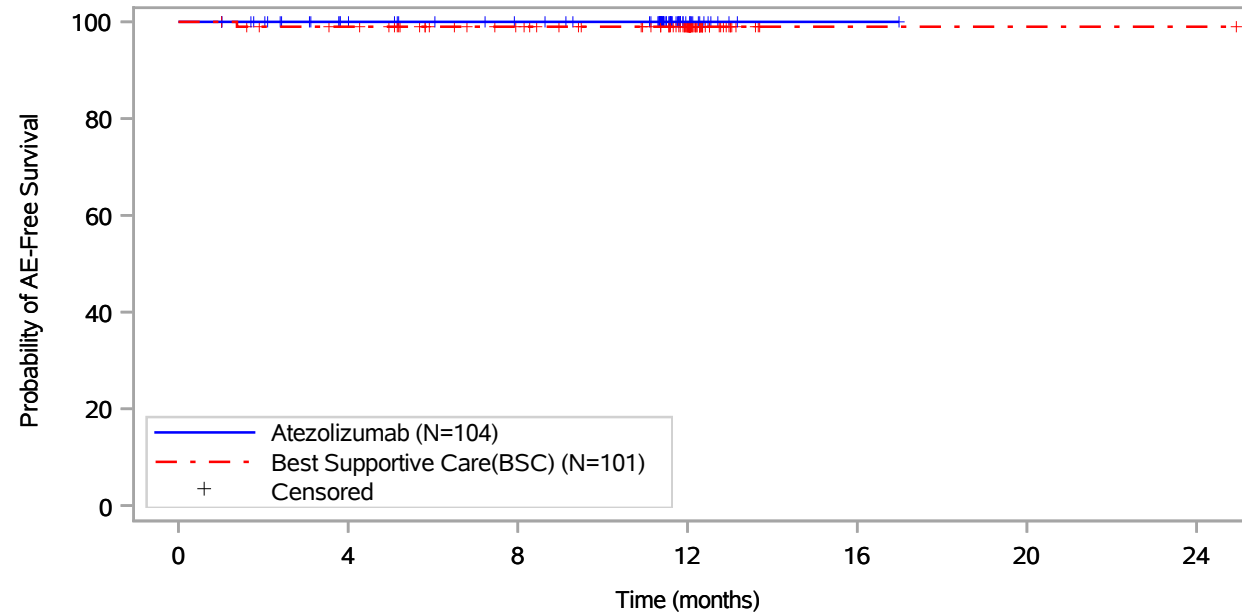
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

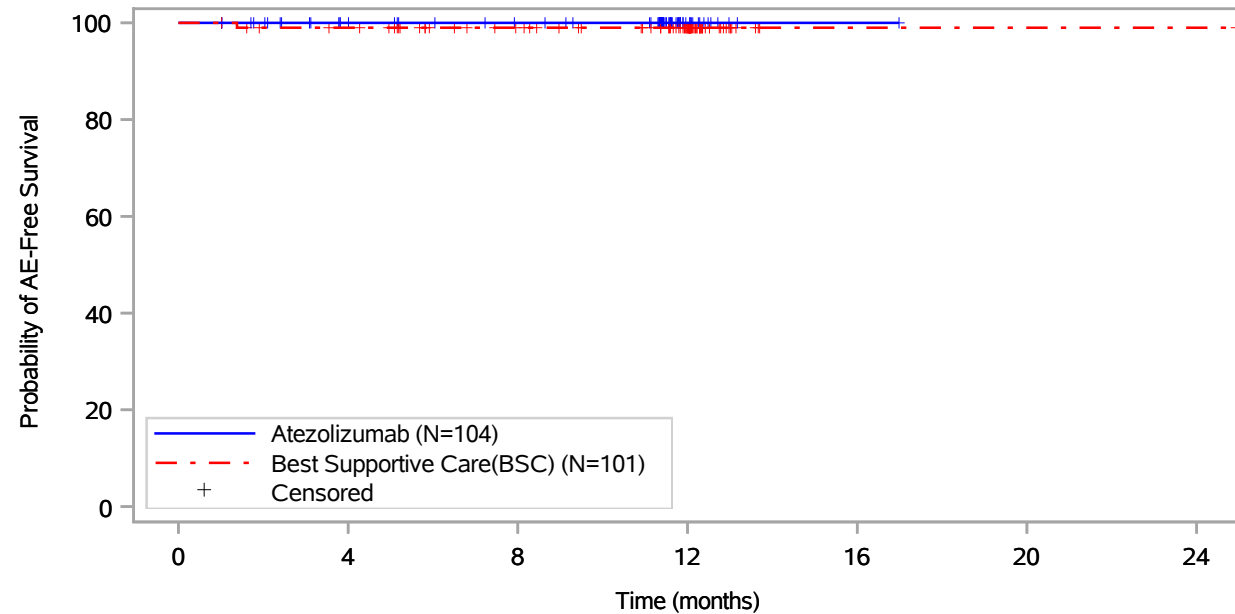
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Dyspnoea



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	82	14	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	96	82	54	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	15	22	90	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99	99

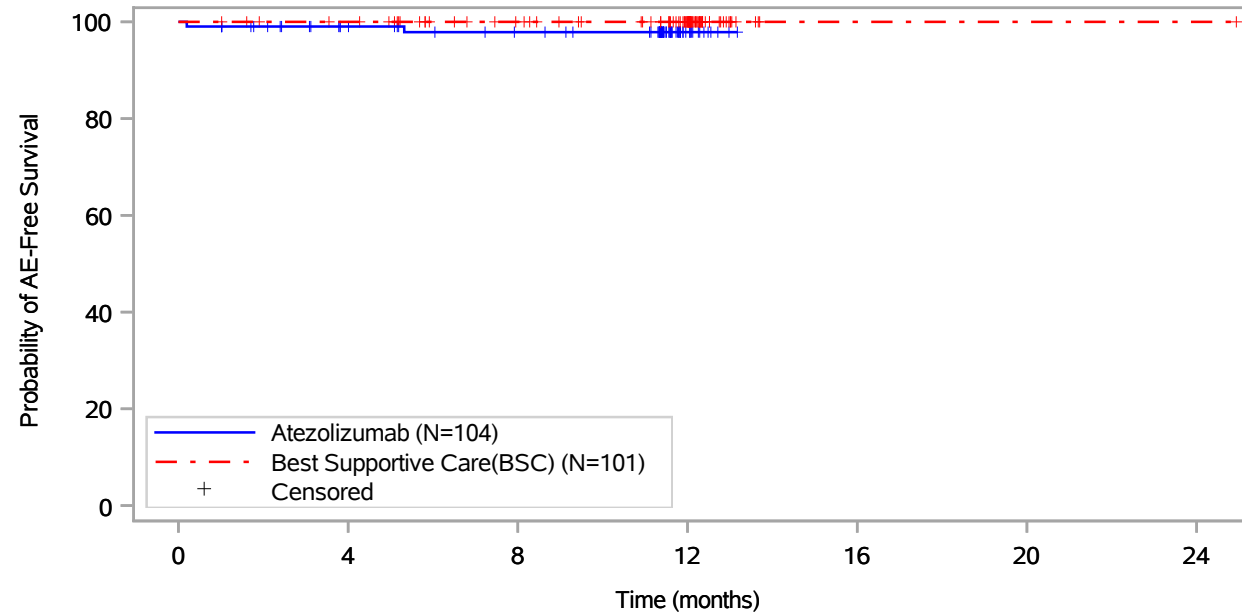
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	89	81	13	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	14	21	89	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100	100

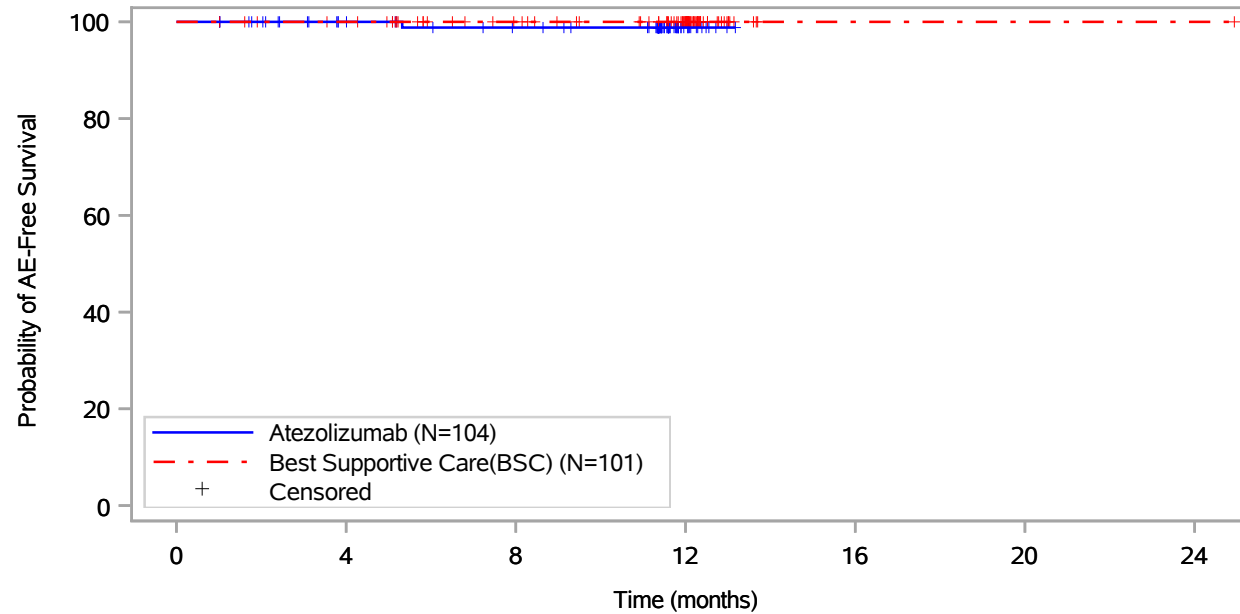
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Parapsoriasis



Patients at risk							
Atezolizumab (N=104)	104	89	81	13	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

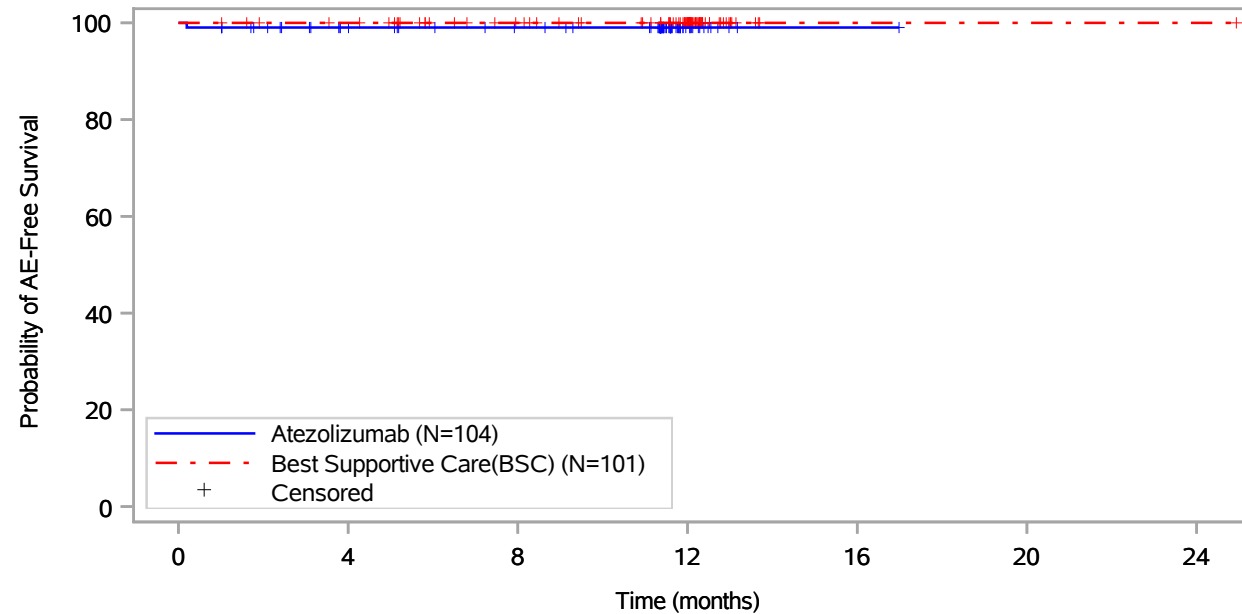
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Rash



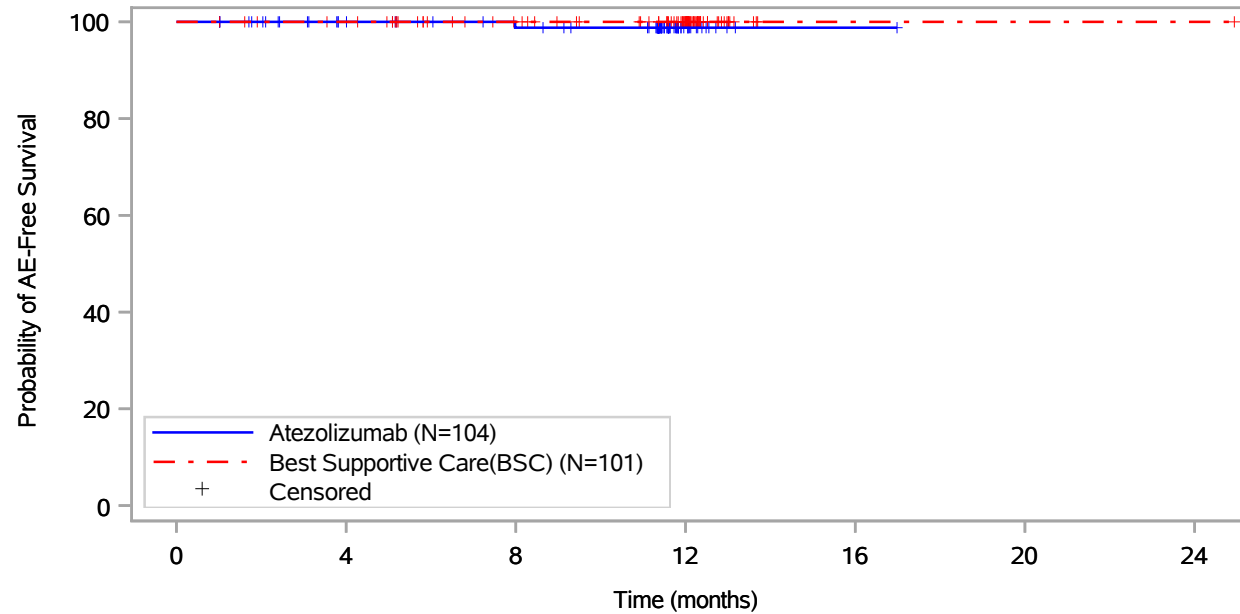
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Vascular disorders, All



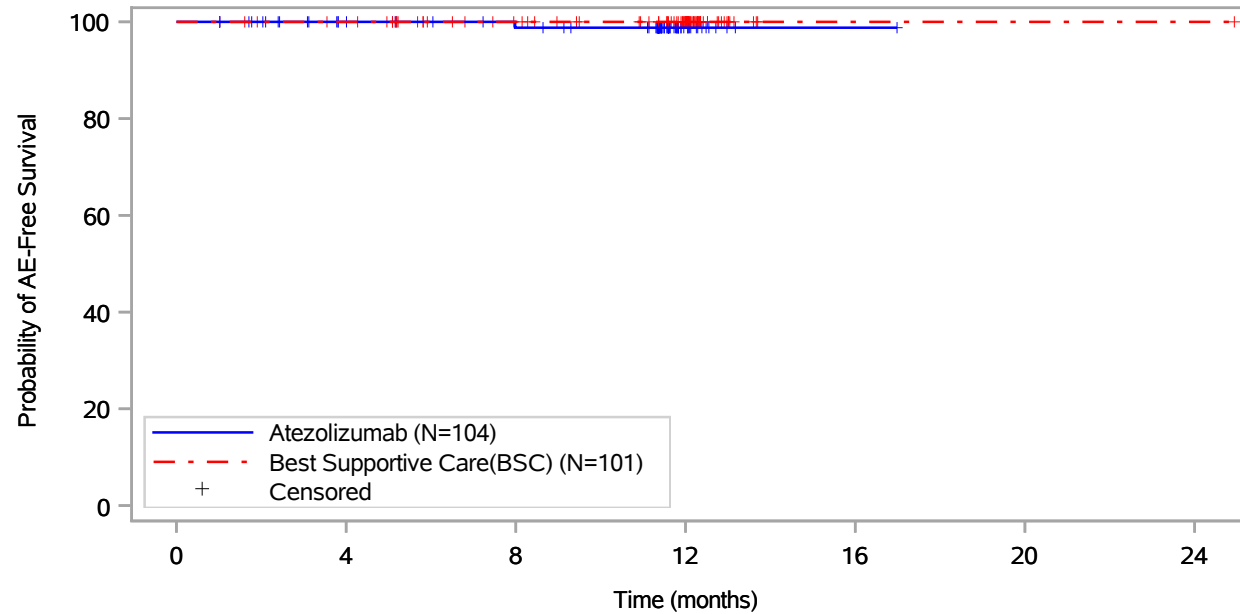
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 3 Adverse Event
STUDY: GO29527
 Vascular disorders, Hypertension



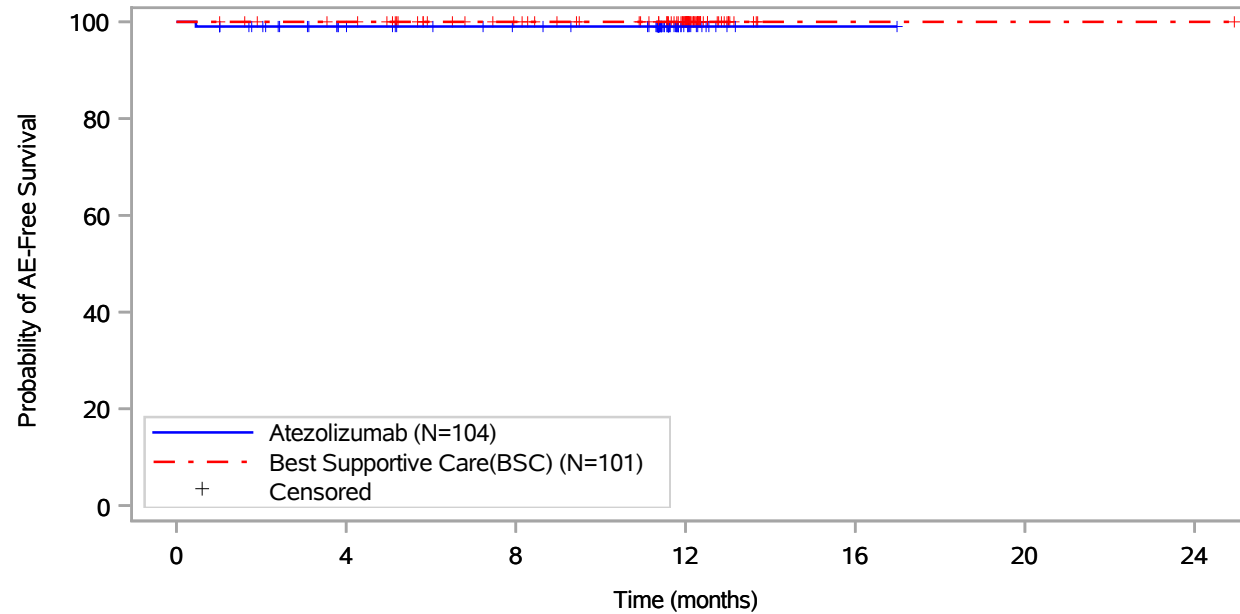
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527
 Endocrine disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

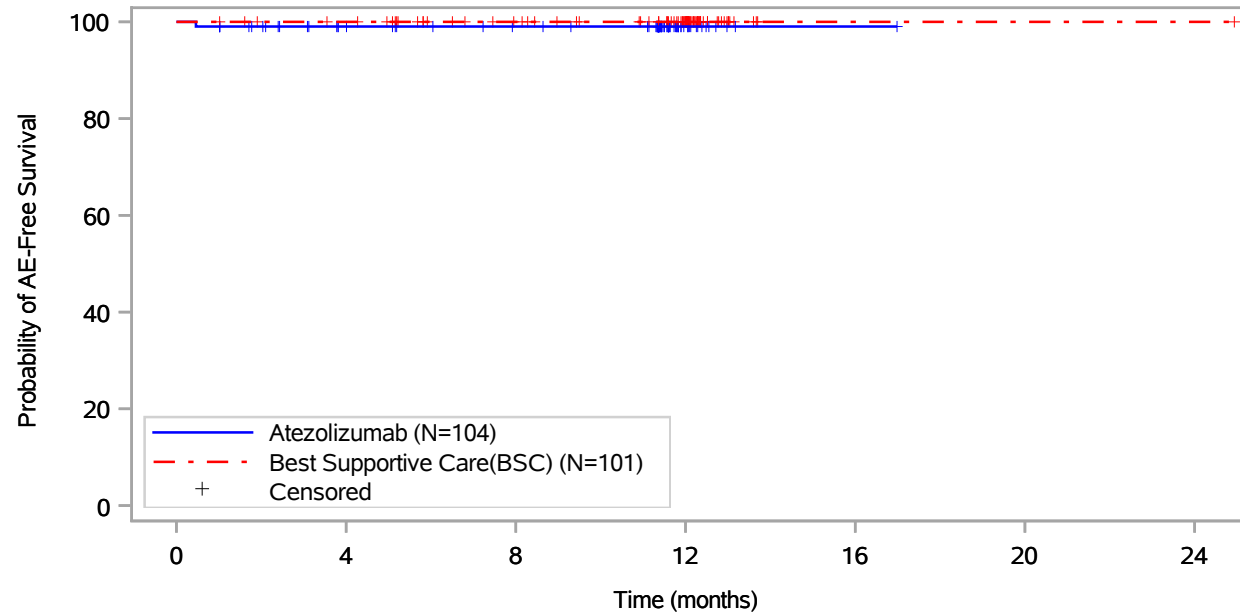
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



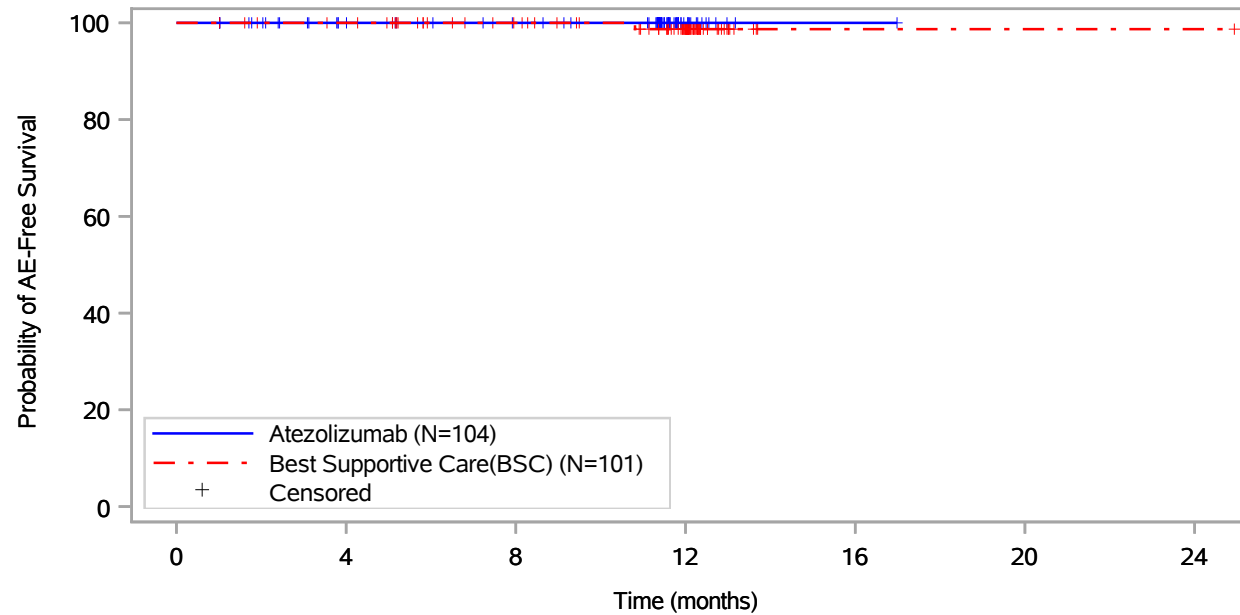
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527
 Investigations, All



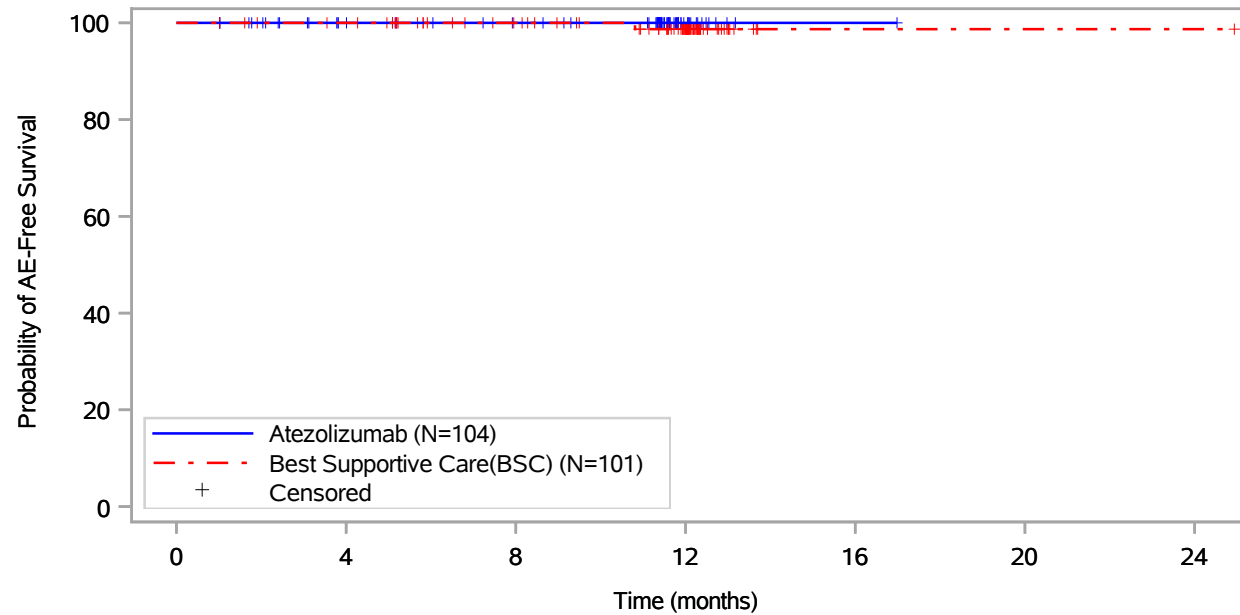
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	83	55	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527
 Investigations, Neutrophil count decreased



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	45	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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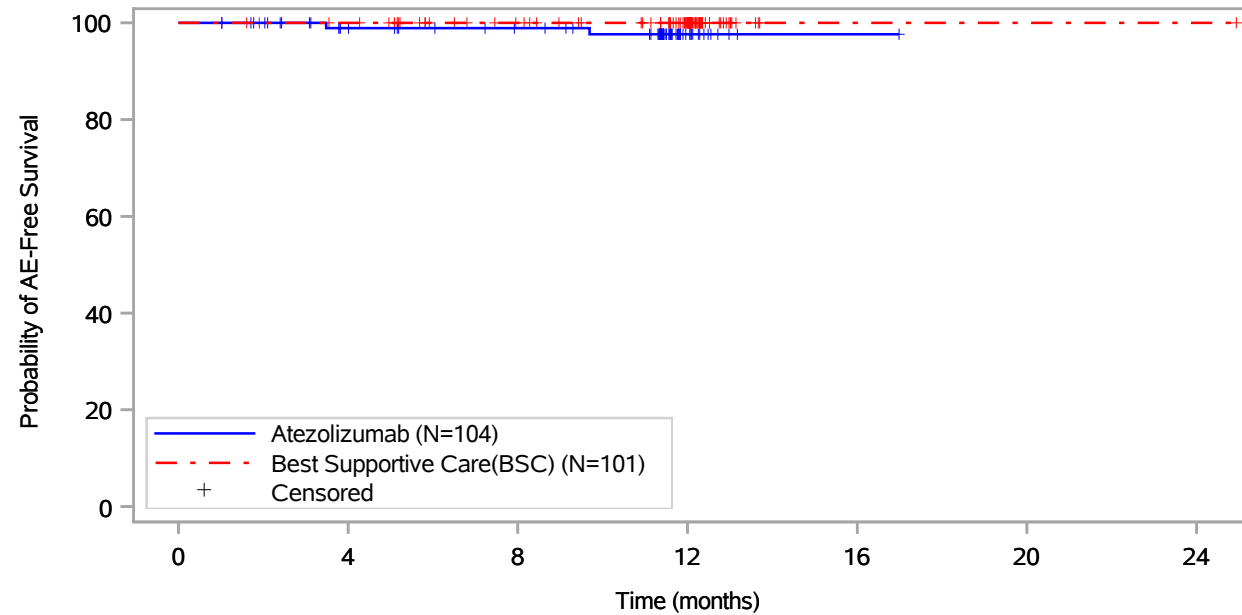
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Metabolism and nutrition disorders, All



Patients at risk							
Atezolizumab (N=104)	104	88	81	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

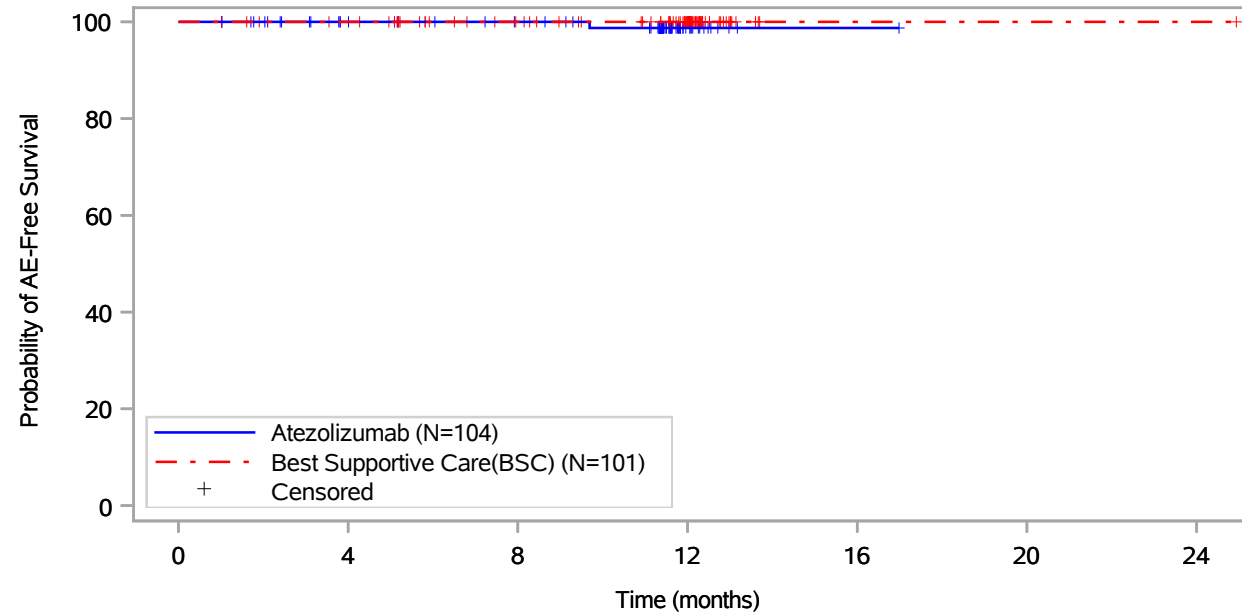
Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

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27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypertriglyceridaemia



Patients at risk							
Atezolizumab (N=104)	104	89	82	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

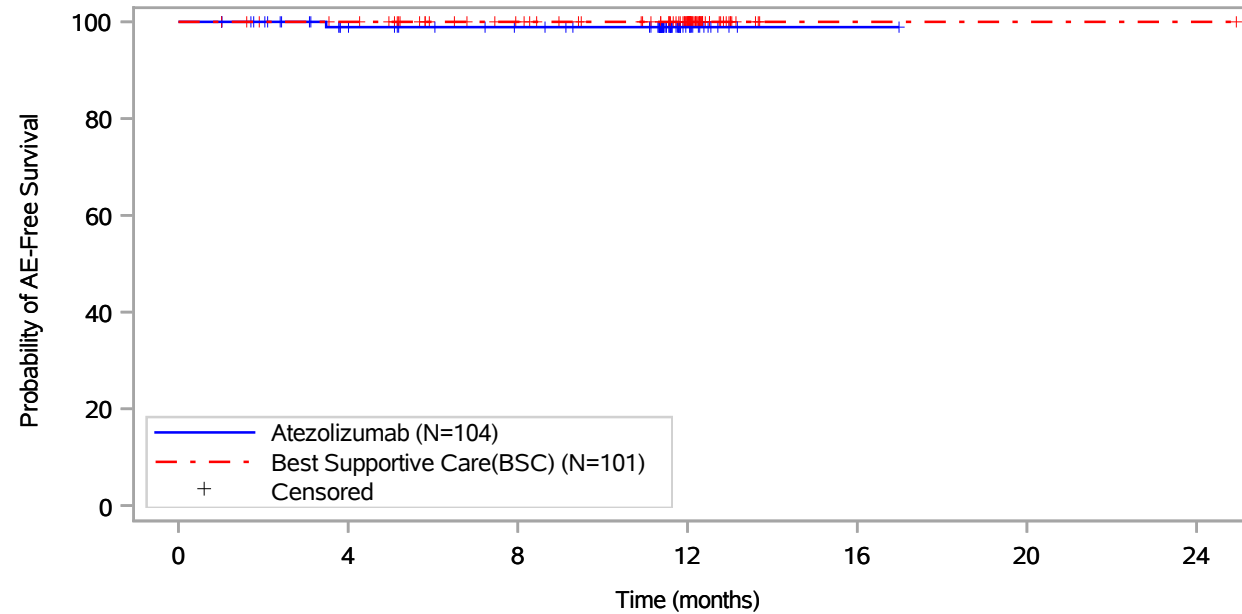
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Metabolism and nutrition disorders, Hypokalaemia



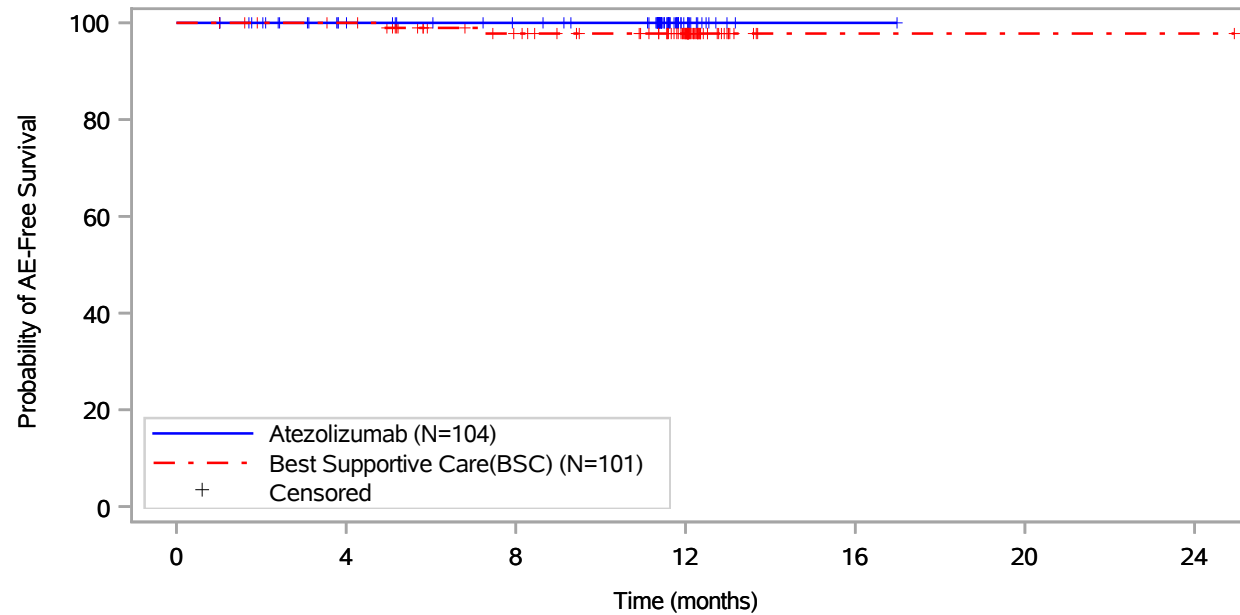
Patients at risk							
Atezolizumab (N=104)	104	88	81	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527
 Nervous system disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	98	98	98

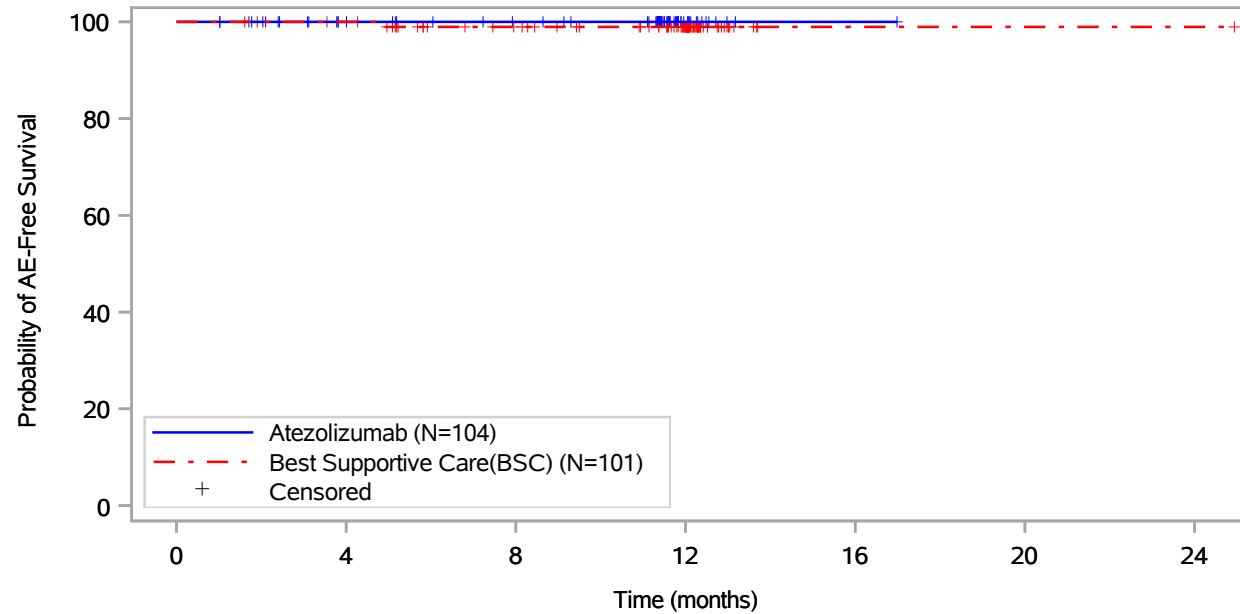
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 Clinical cut-off: 18APR2022

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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Nervous system disorders, Brain oedema



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	45	99	99	99

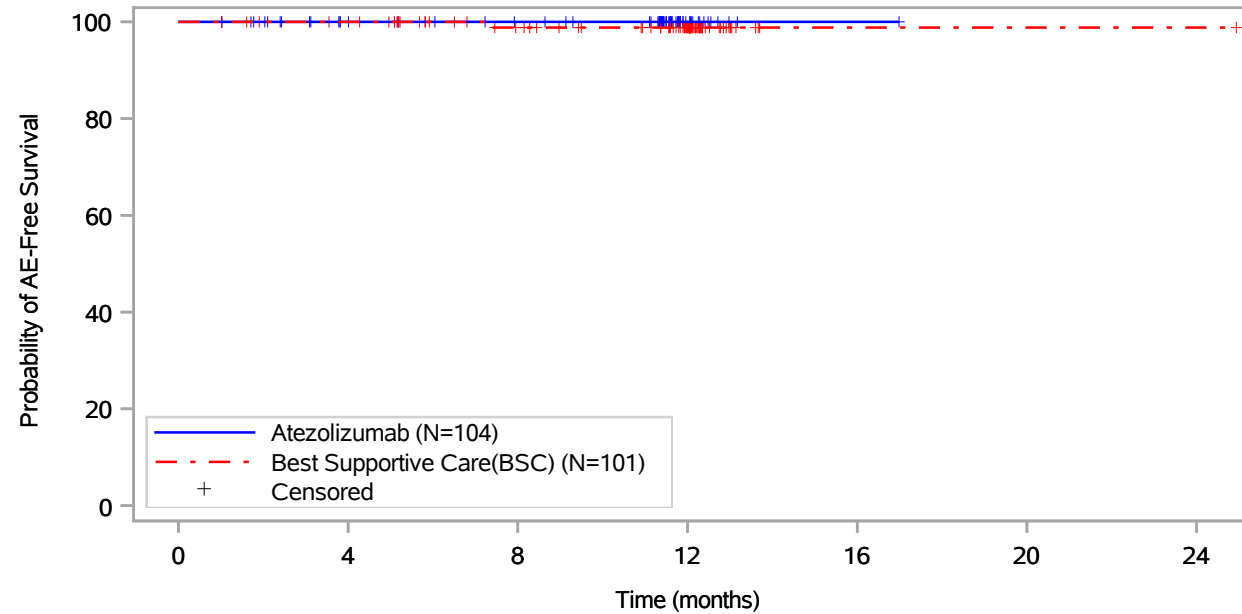
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..._OS_IA/prod/output/g_km_soc_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	99	99	99

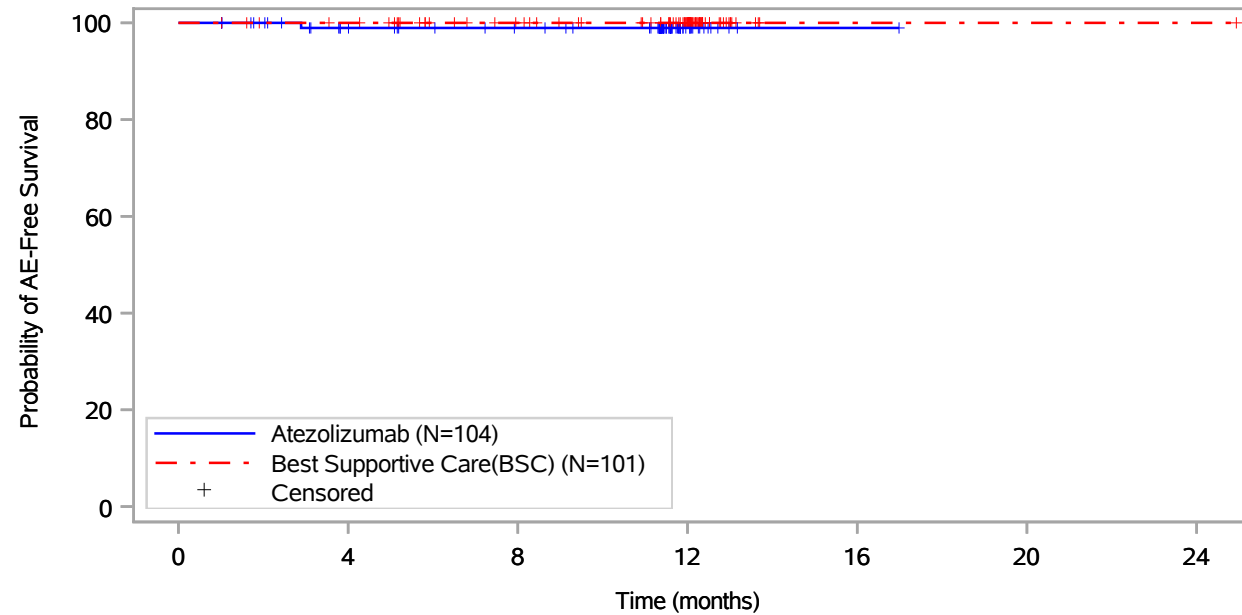
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 4 Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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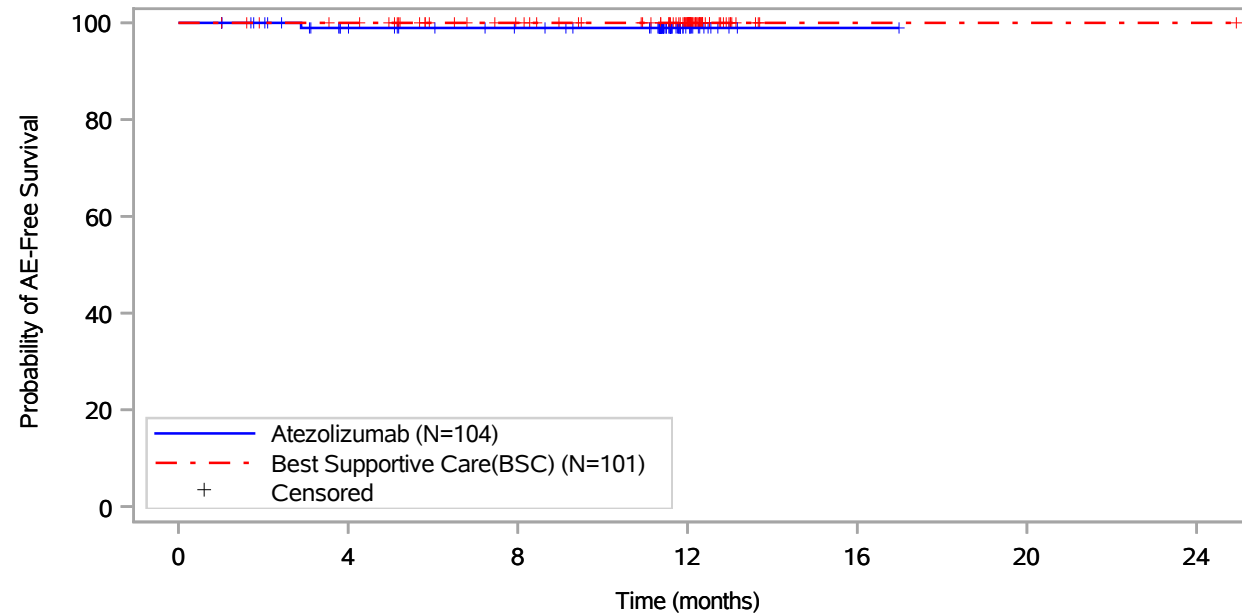
Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Time to First Grade 4 Adverse Event

STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



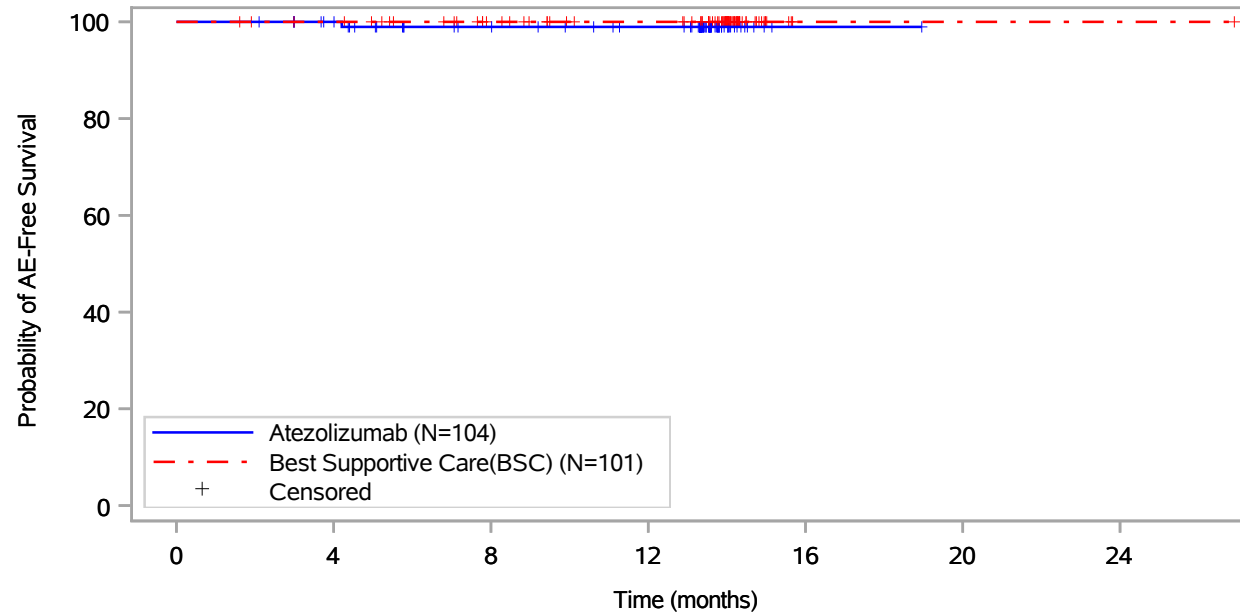
Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	89	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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27JUN2022 20:49

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Blood and lymphatic system disorders, All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

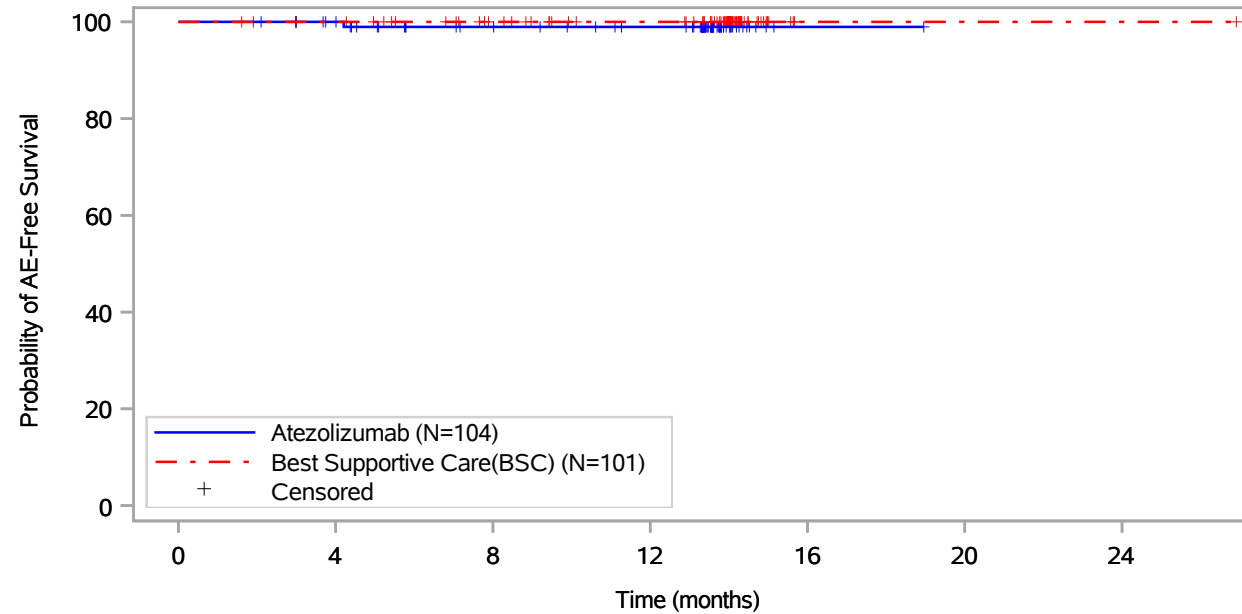
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Blood and lymphatic system disorders, Sarcoidosis of lymph node



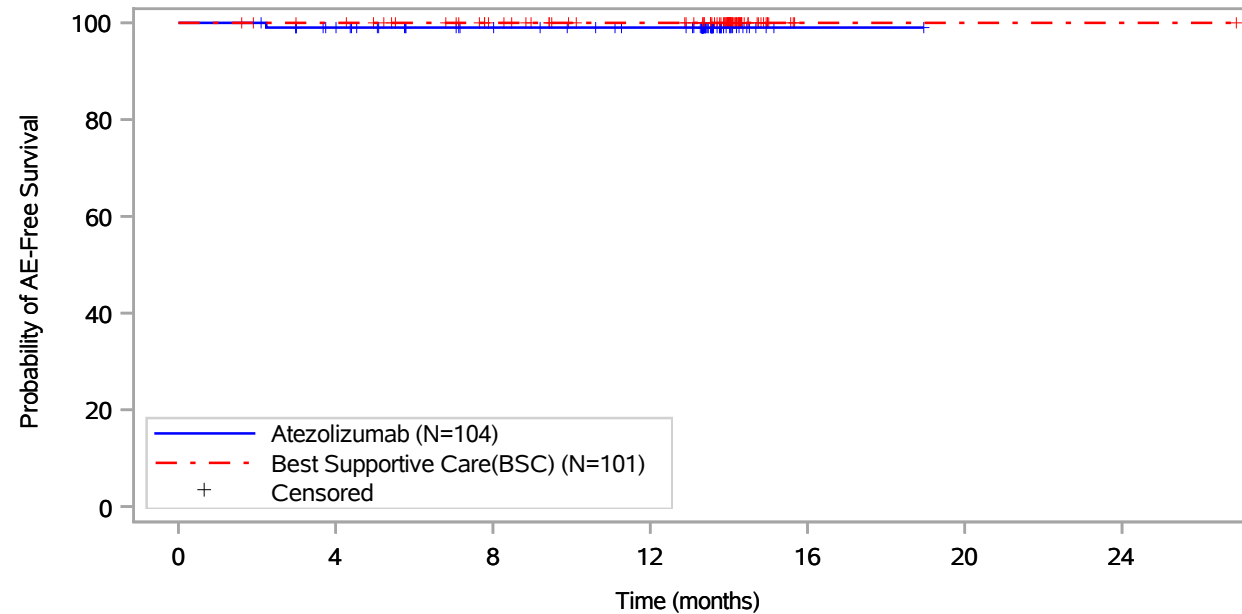
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Cardiac disorders, All



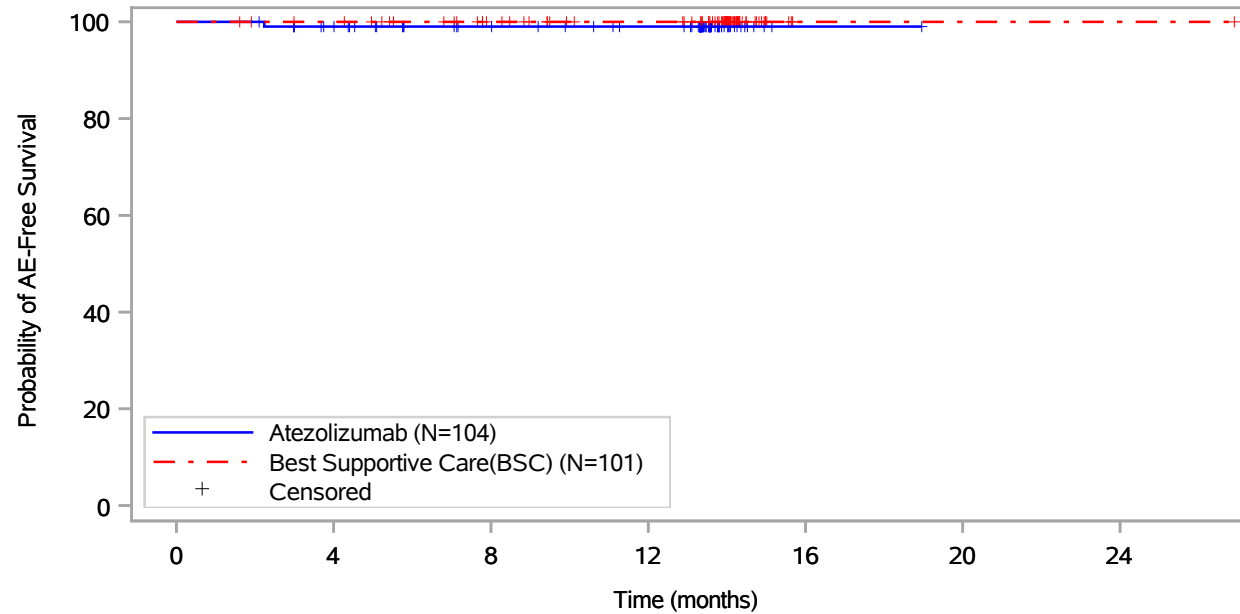
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	96	84	78	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Cardiac disorders, Atrial fibrillation



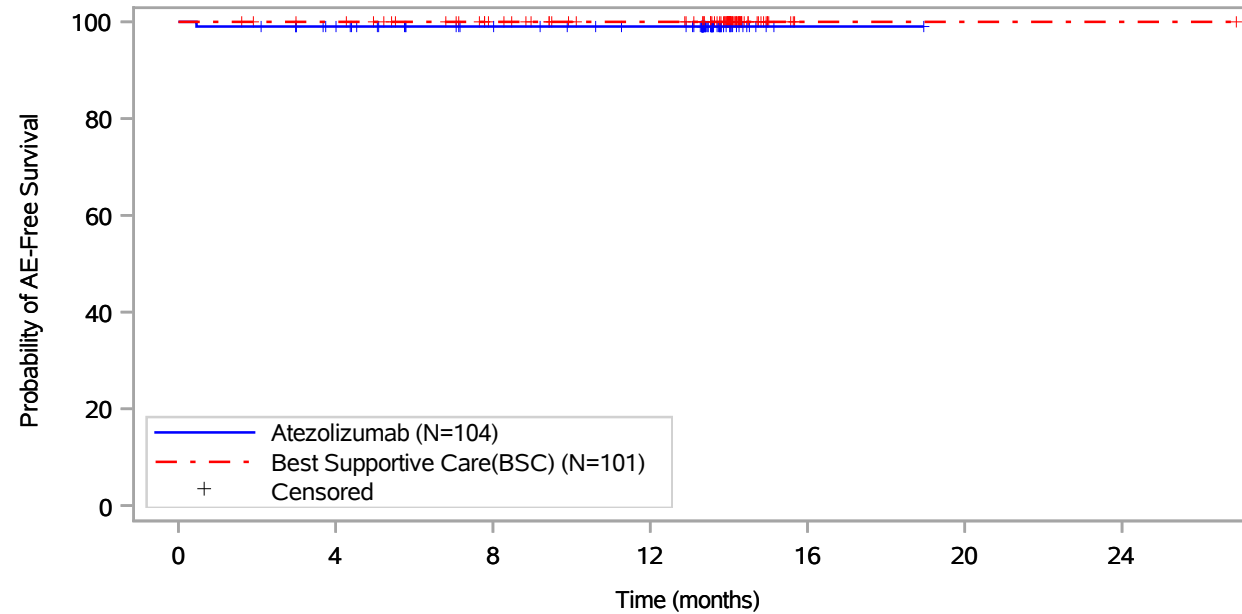
Patients at risk							
Atezolizumab (N=104)	104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Endocrine disorders, All



Patients at risk							
Atezolizumab (N=104)	104	96	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

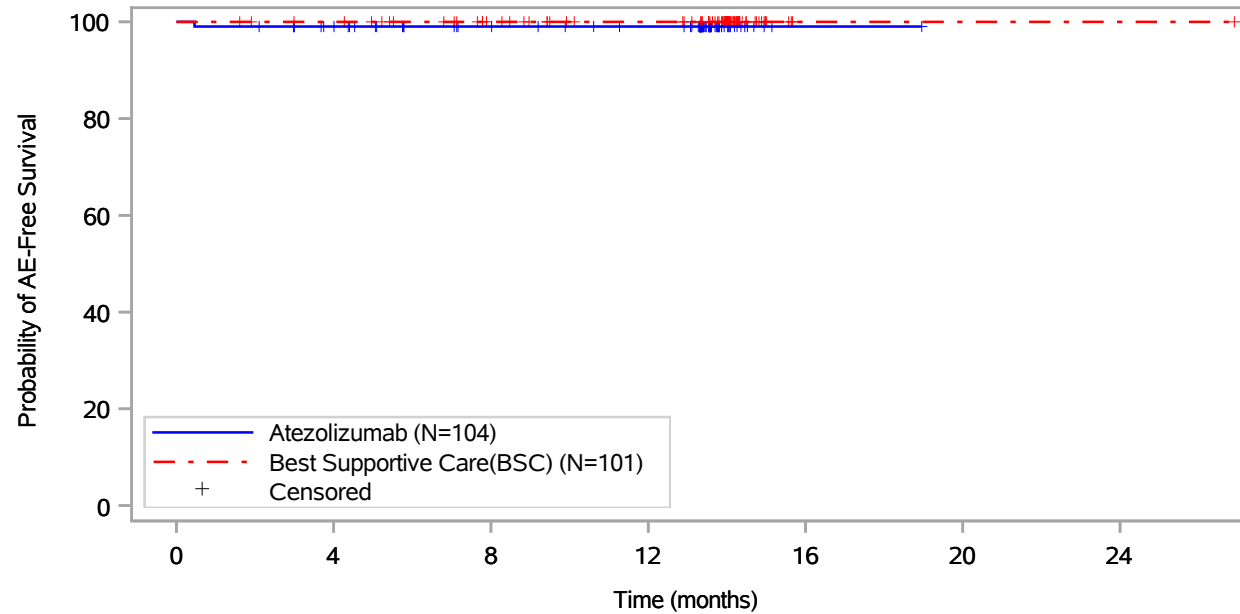
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Endocrine disorders, Inappropriate antidiuretic hormone secretion



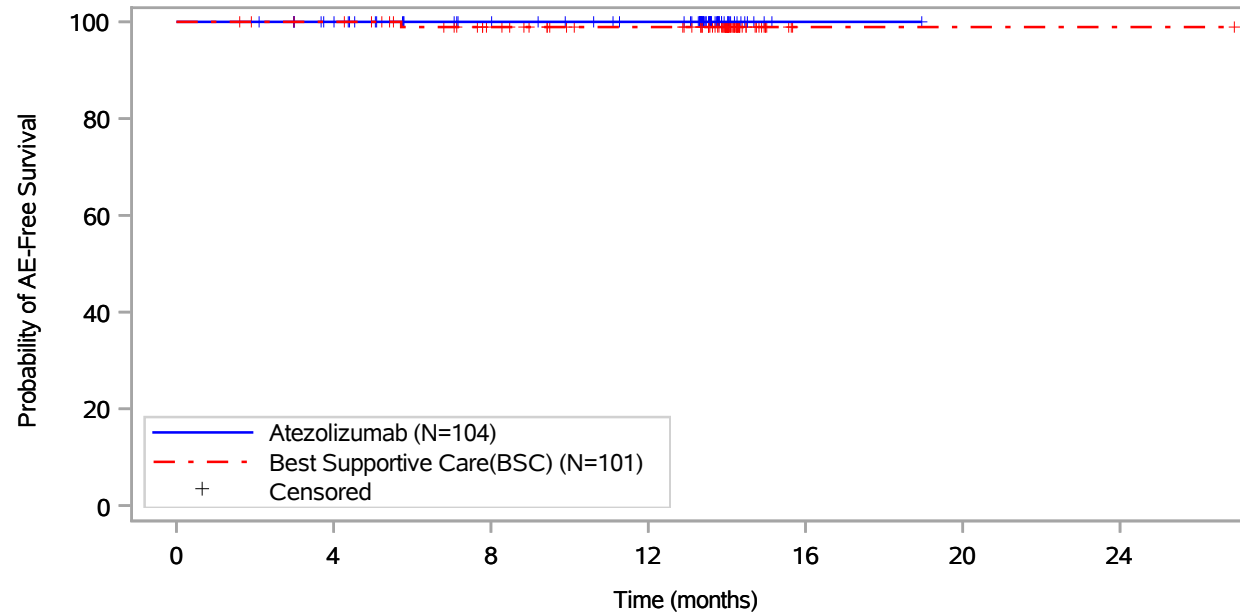
Patients at risk							
Atezolizumab (N=104)	104	96	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Eye disorders, All



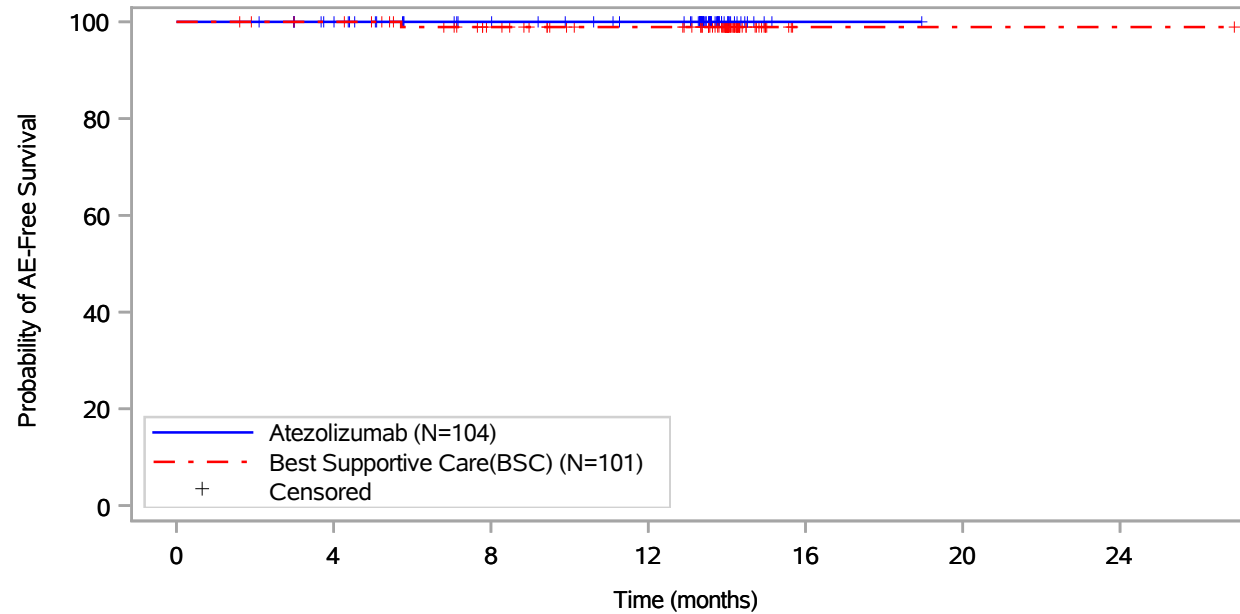
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	85	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Eye disorders, Vitreous haemorrhage



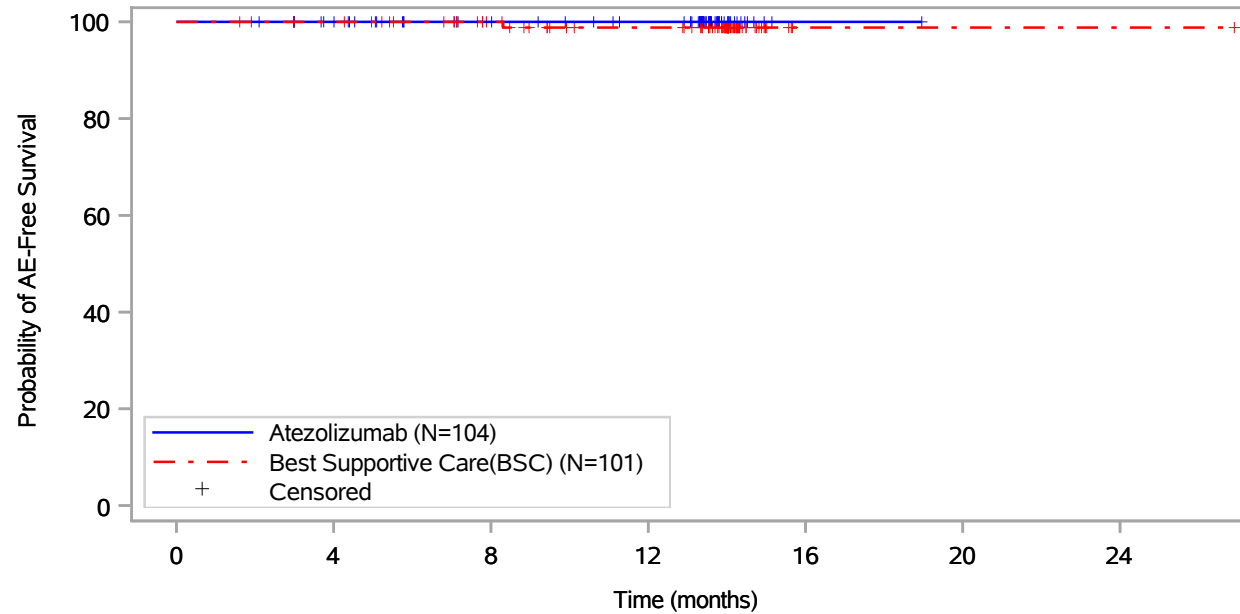
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	85	76	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Gastrointestinal disorders, All



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

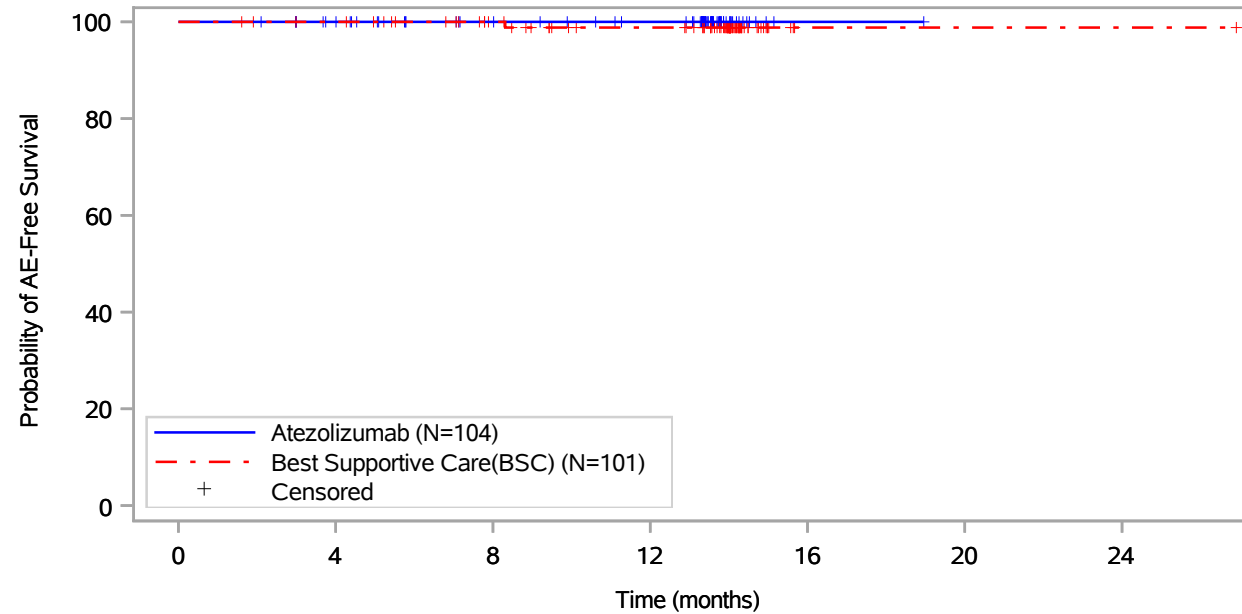
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Gastrointestinal disorders, Abdominal hernia



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

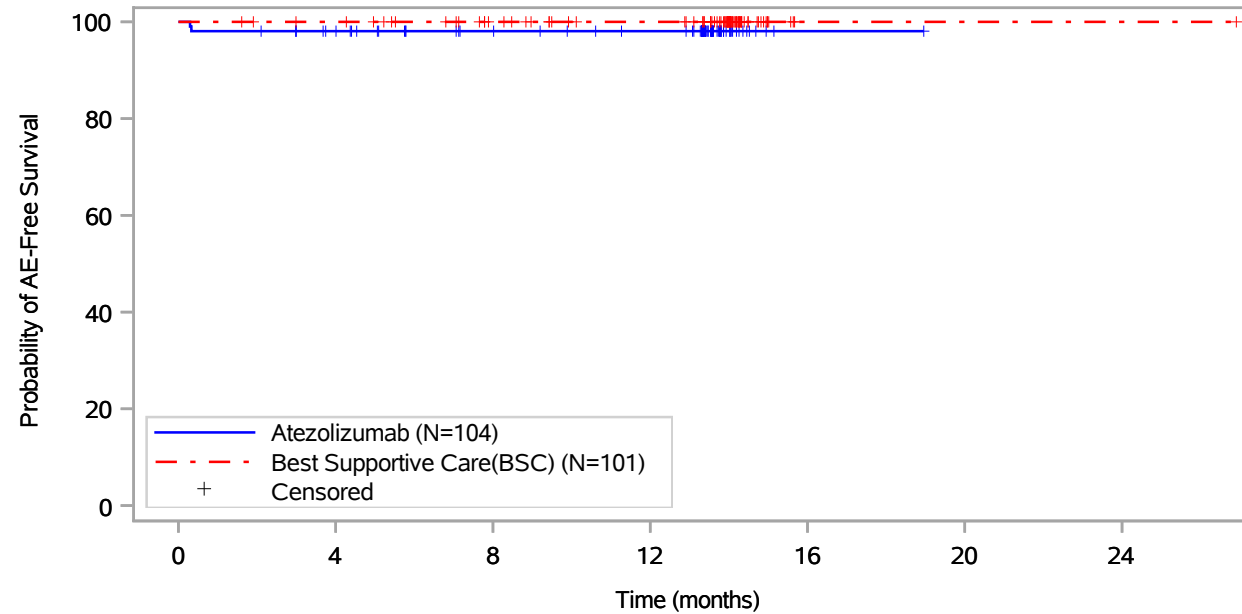
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk							
Atezolizumab (N=104)	104	96	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

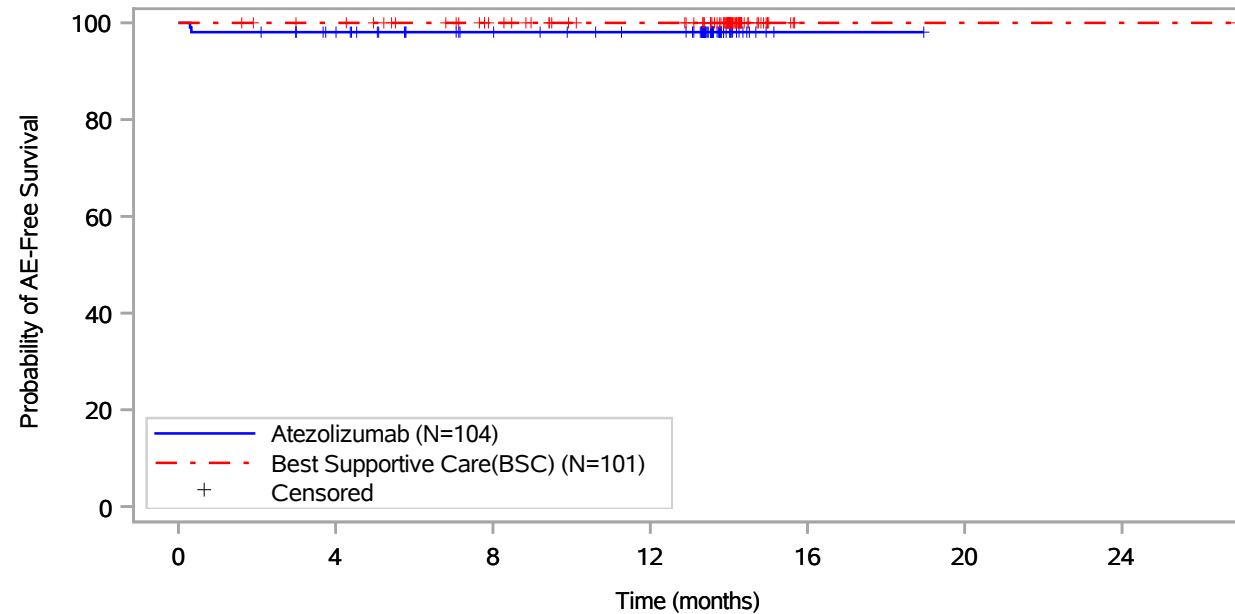
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pyrexia



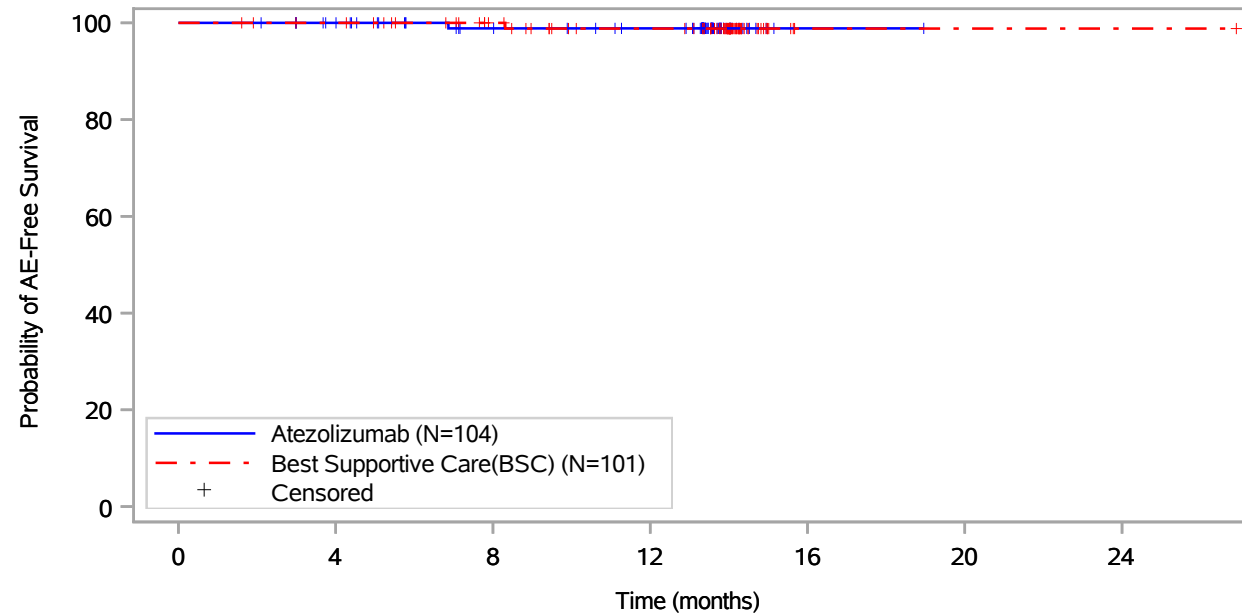
Patients at risk							
Atezolizumab (N=104)	104	96	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, All



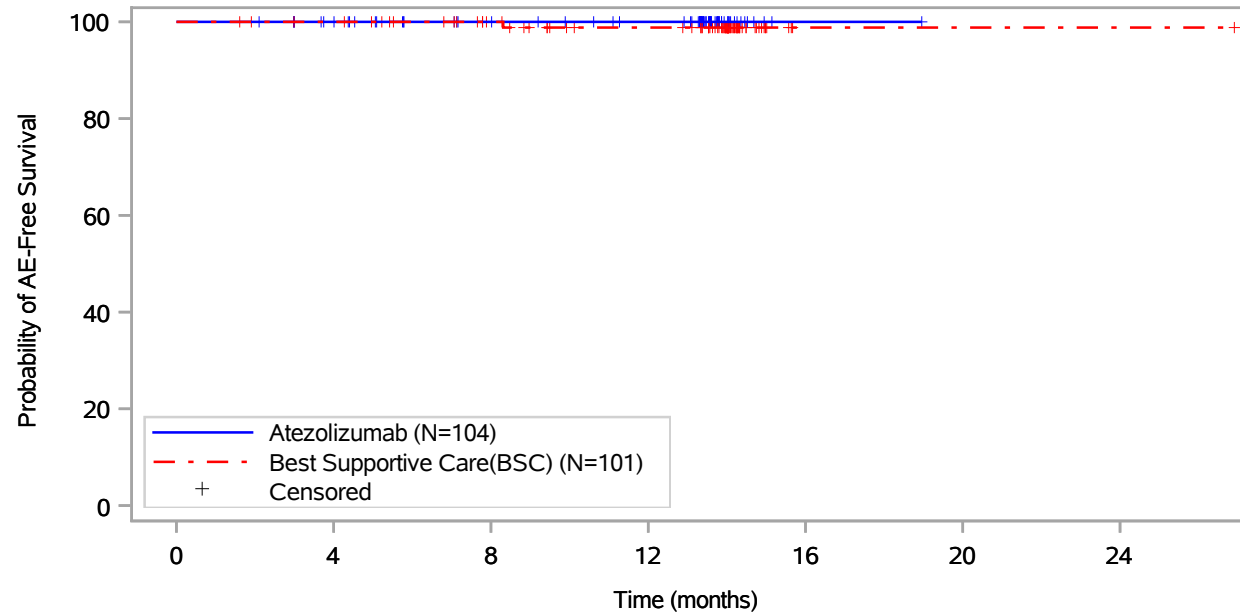
Patients at risk							
Atezolizumab (N=104)	104	97	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
 Output: ..CE_OS_IA/prod/output/g_km_soc_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Cholestasis



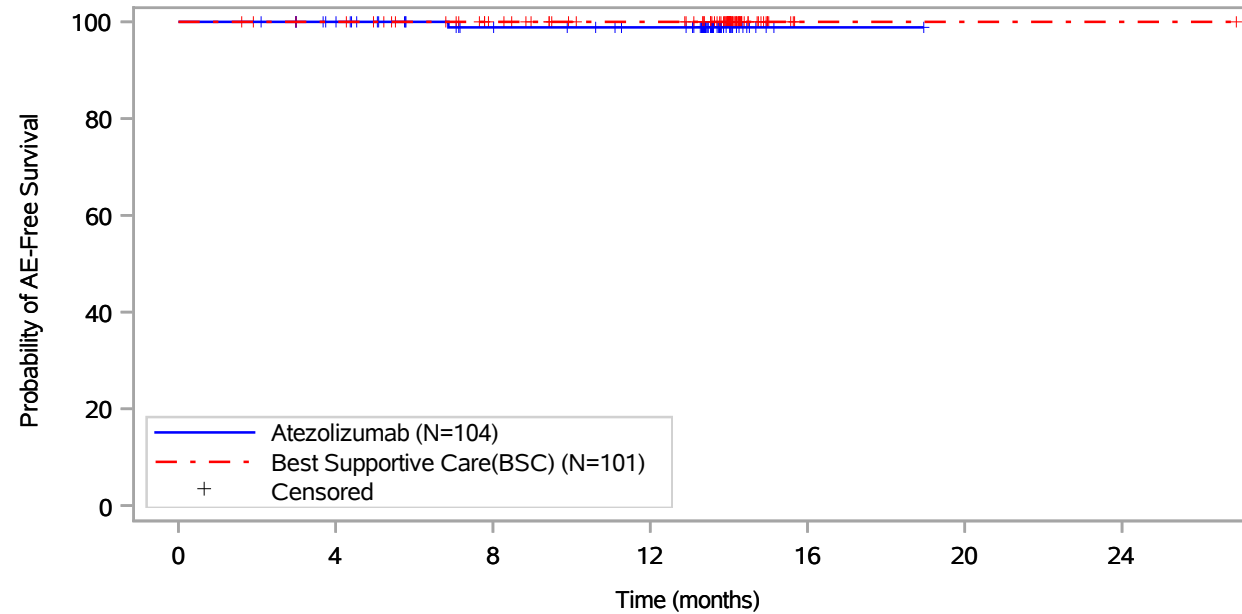
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	76	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Hepatobiliary disorders, Drug-induced liver injury



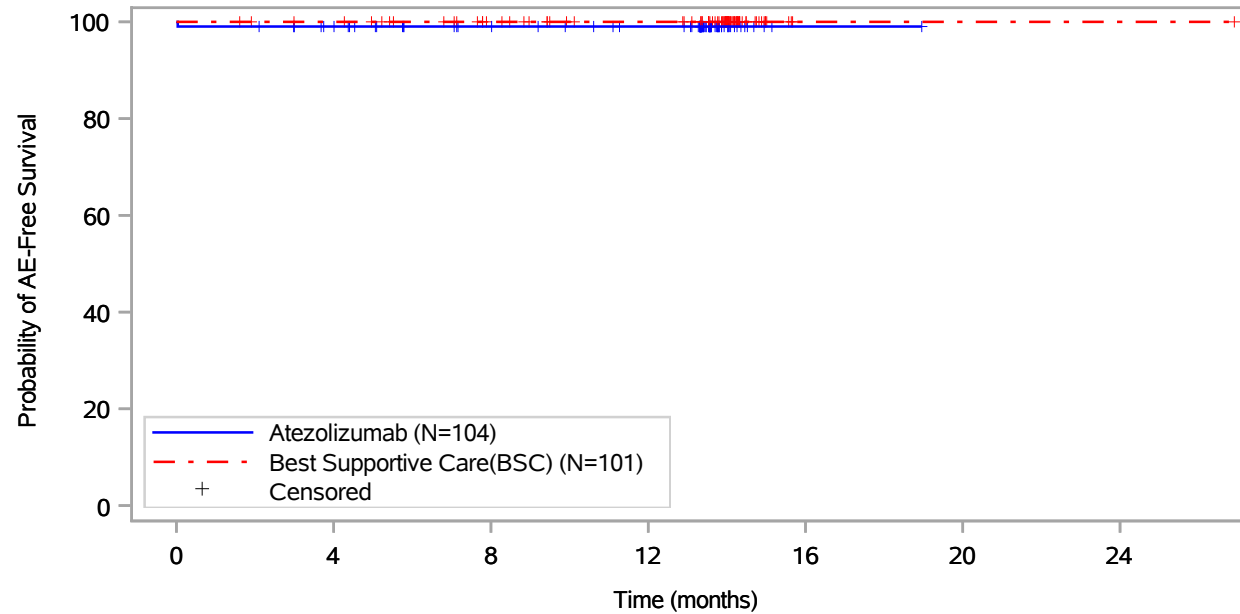
Patients at risk							
Atezolizumab (N=104)	104	97	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Immune system disorders, All



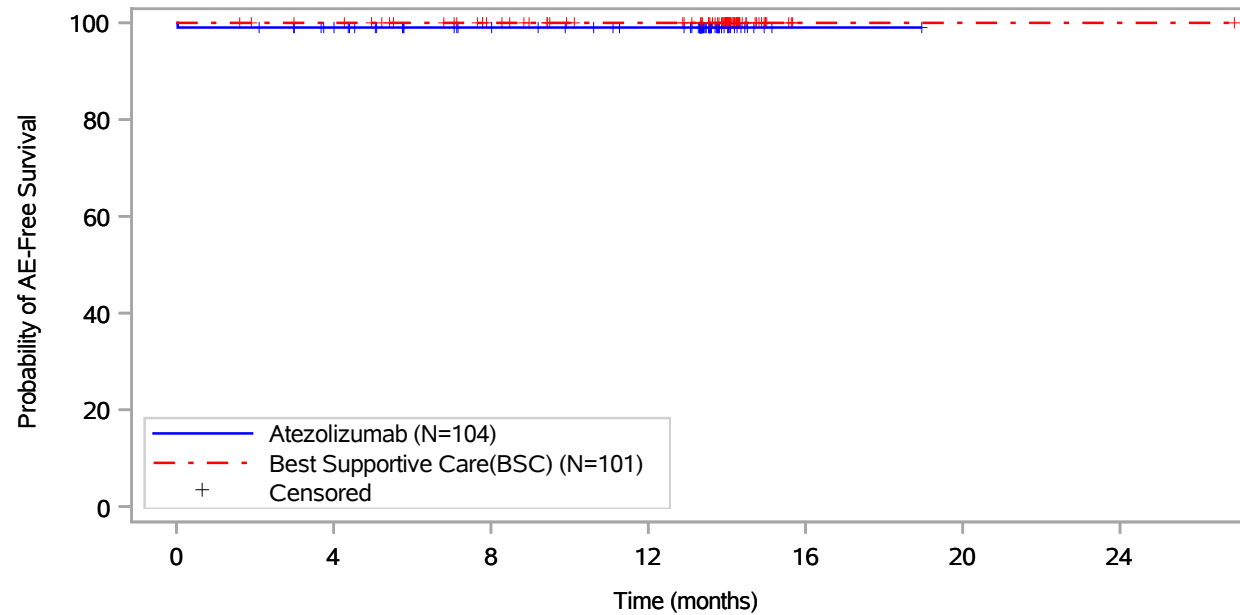
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Immune system disorders, Hypersensitivity



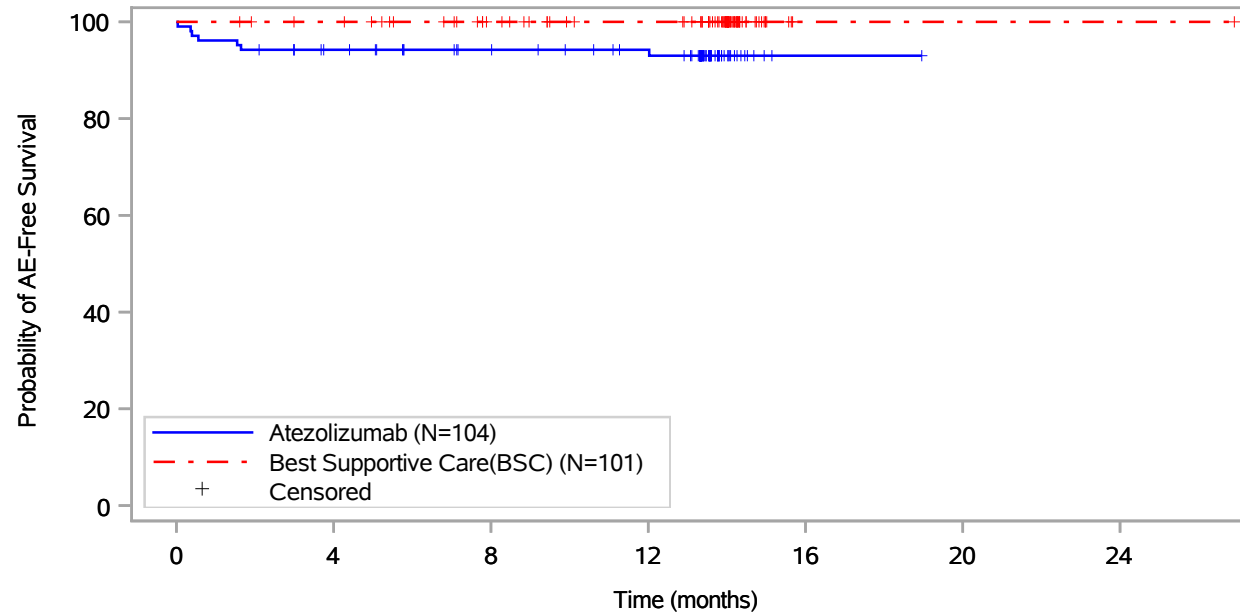
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, All



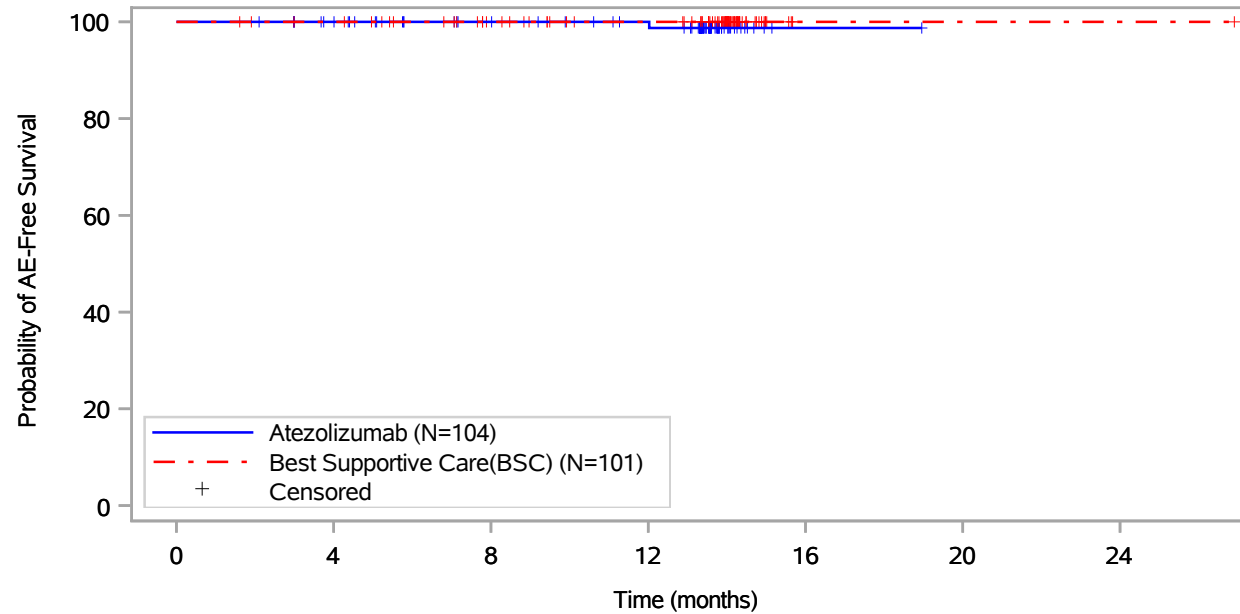
Patients at risk							
Atezolizumab (N=104)	104	92	83	77	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	15	21	96	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Cellulitis



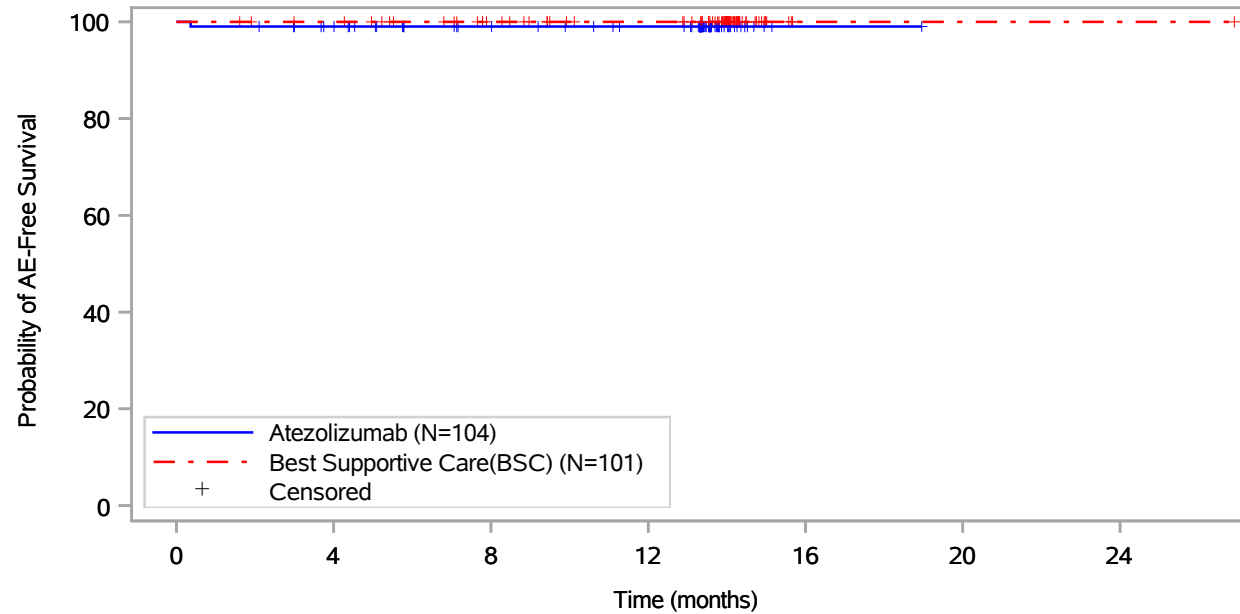
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Encephalitis



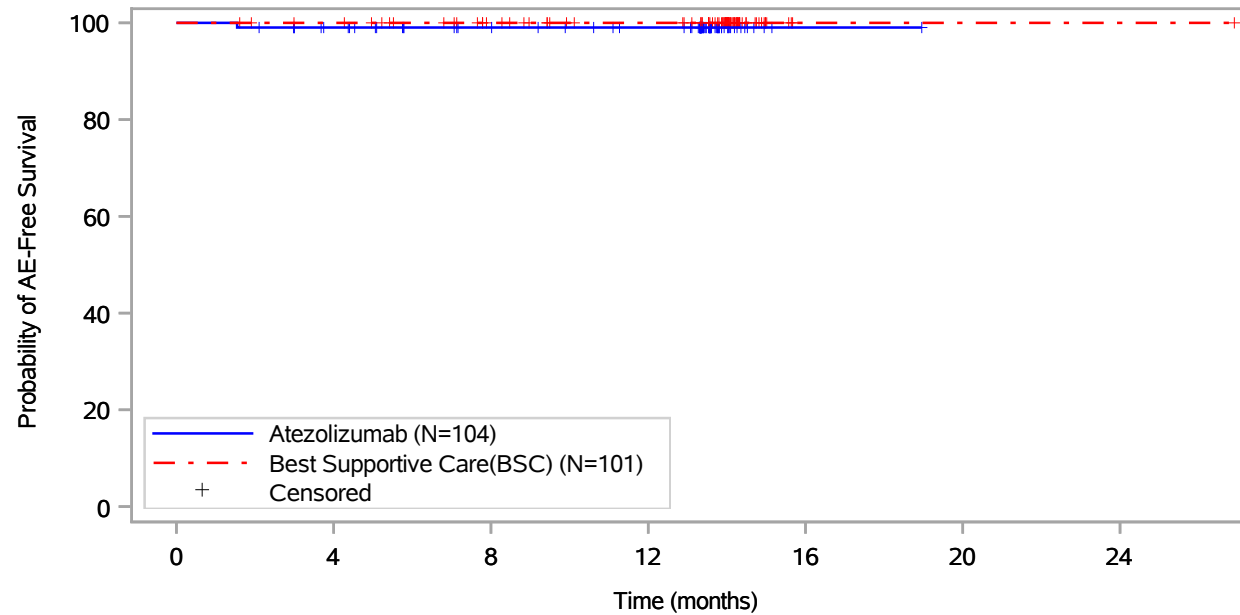
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Meningitis



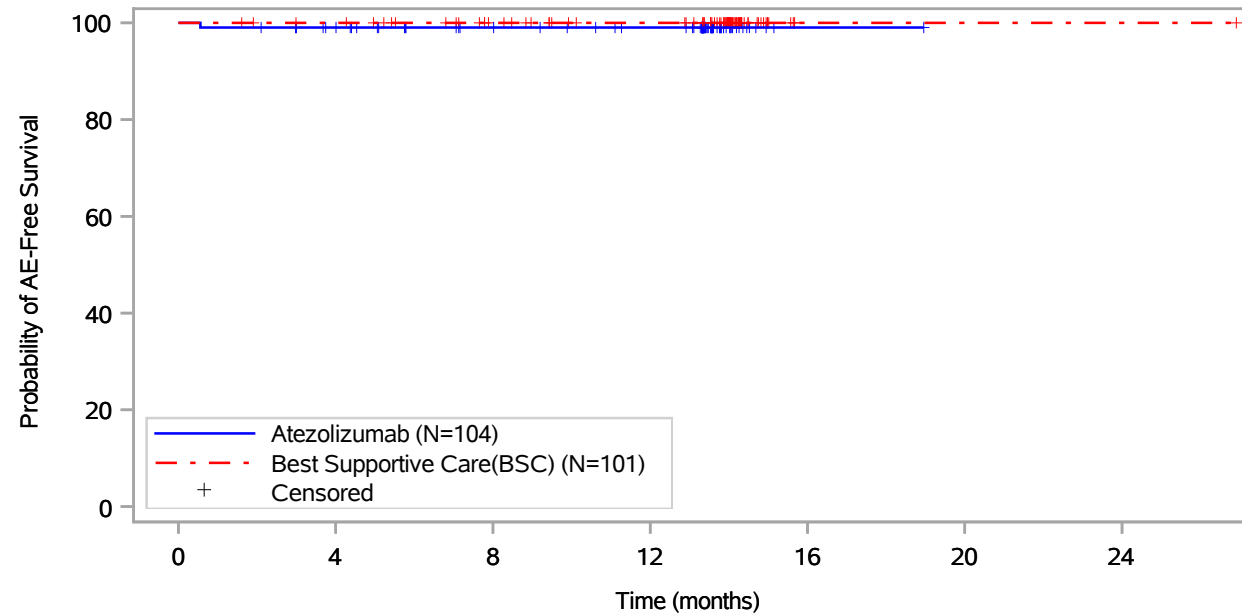
Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Pneumonia



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

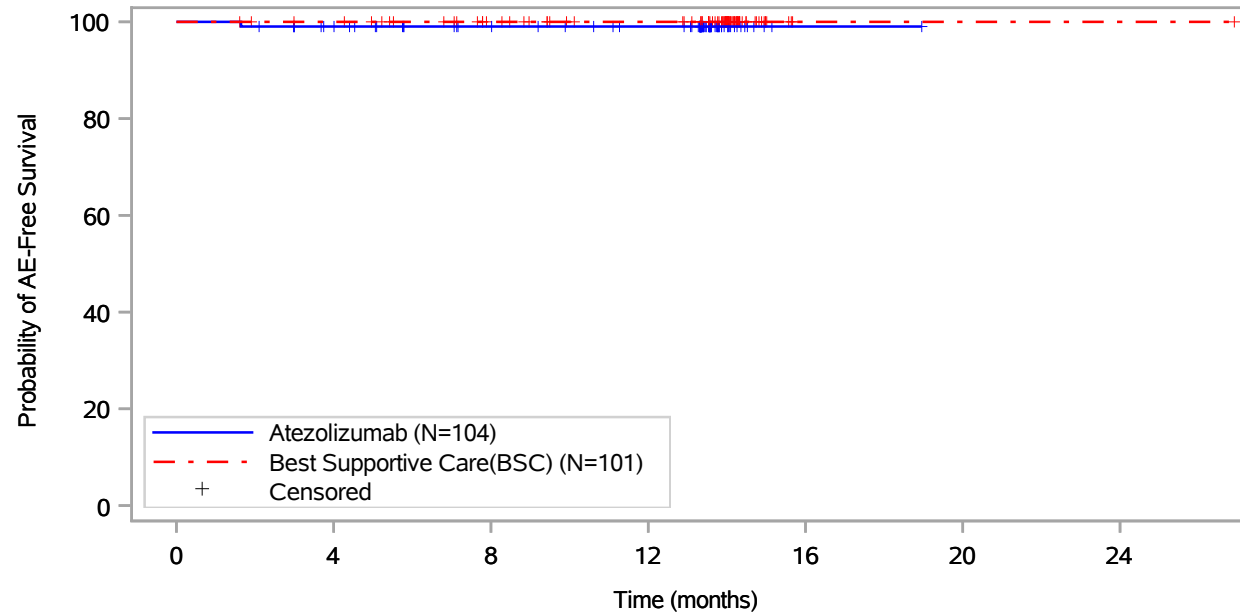
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Infections and infestations, Pneumonia pneumococcal



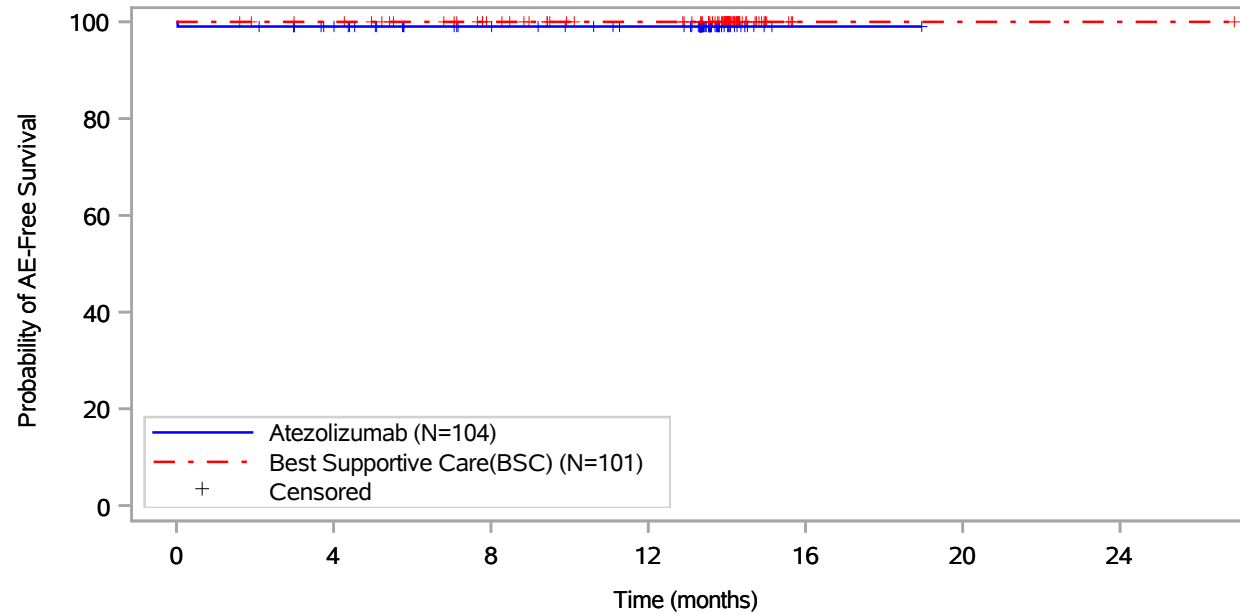
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Sepsis



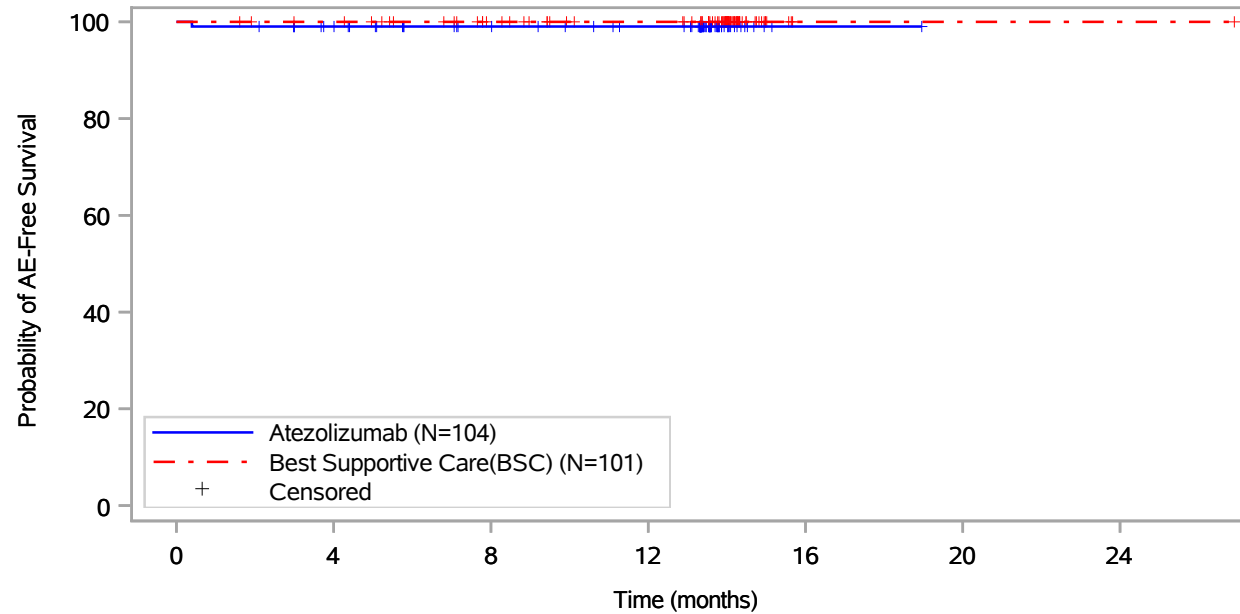
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	96	84	78	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Infections and infestations, Tonsillitis



Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

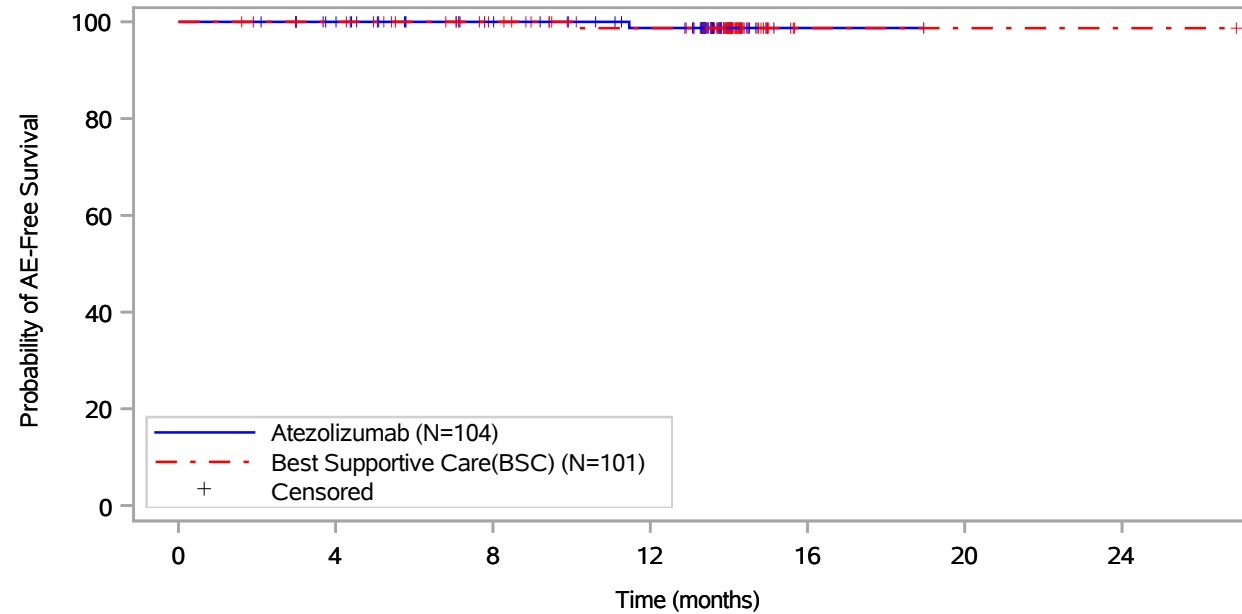
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), All



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	78	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	76	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99	99

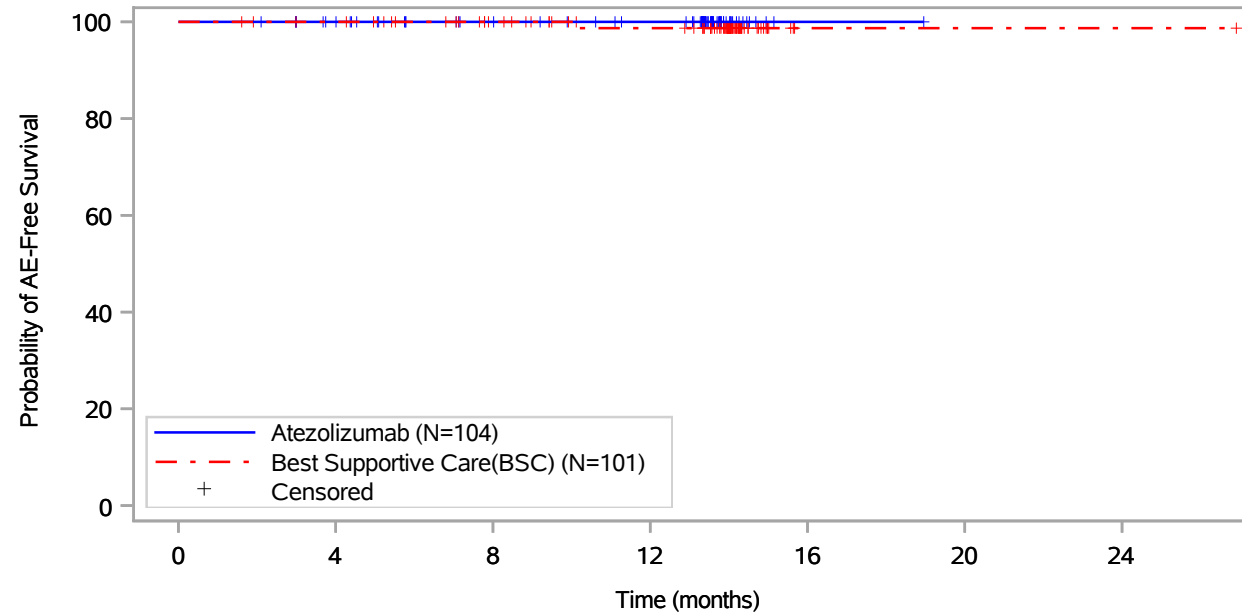
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Pancreatic carcinoma



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

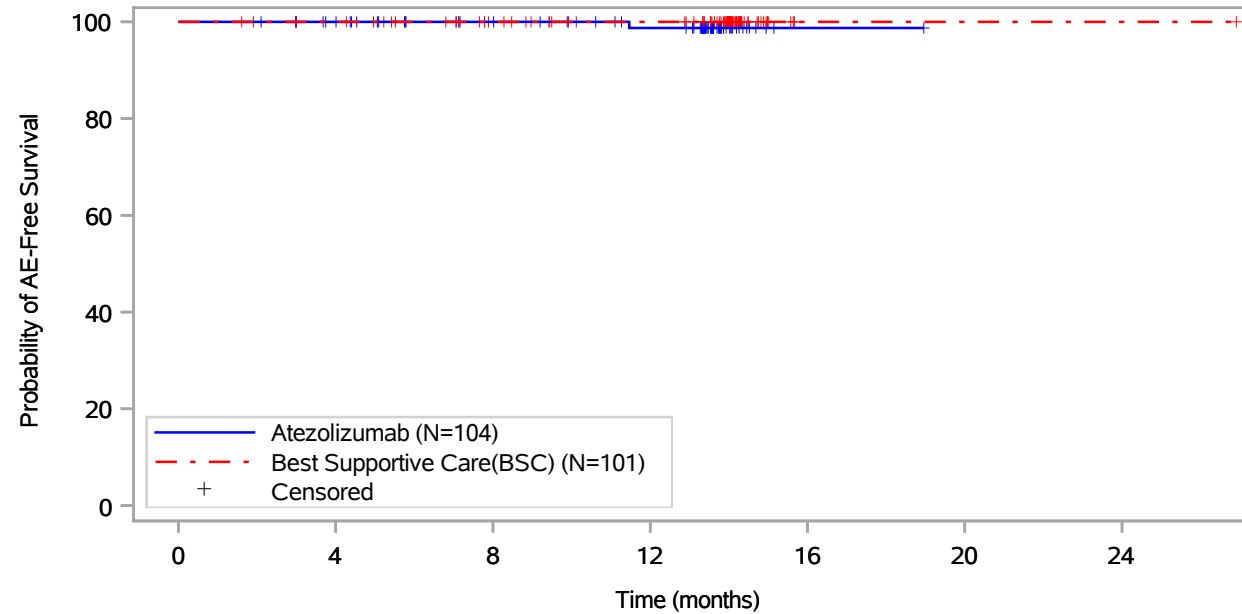
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Neoplasms benign, malignant and unspecified (incl cysts and polyps), Squamous cell carcinoma of skin



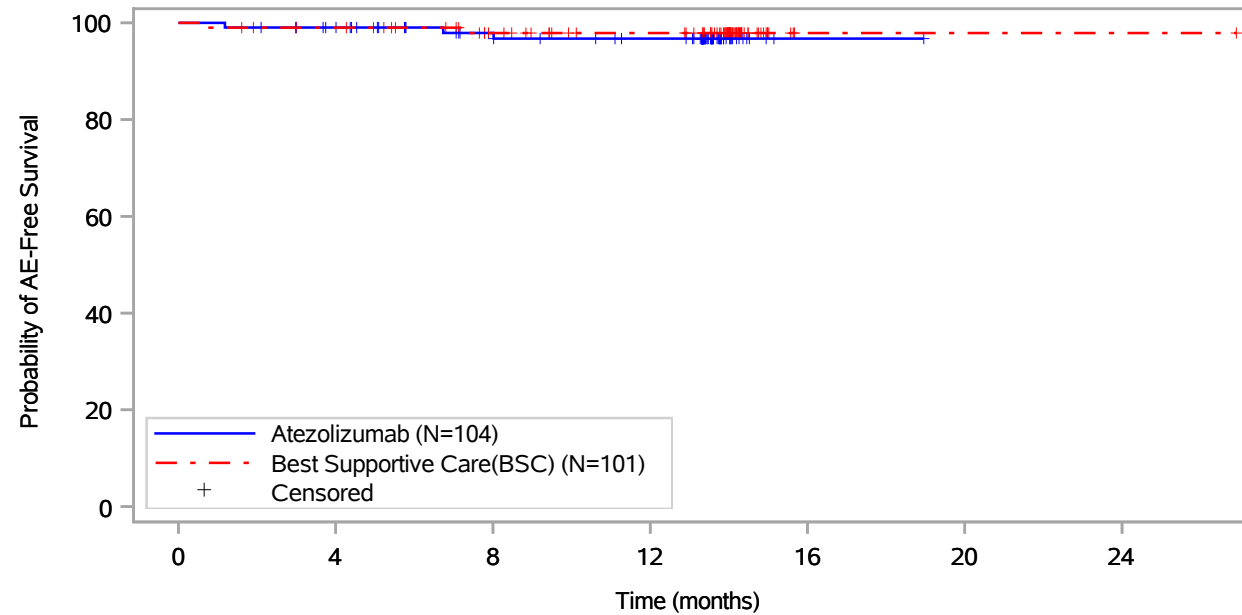
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	78	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	102	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Nervous system disorders, All



Patients at risk							
Atezolizumab (N=104)	104	97	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	84	75	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	23	100	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	98	98	98

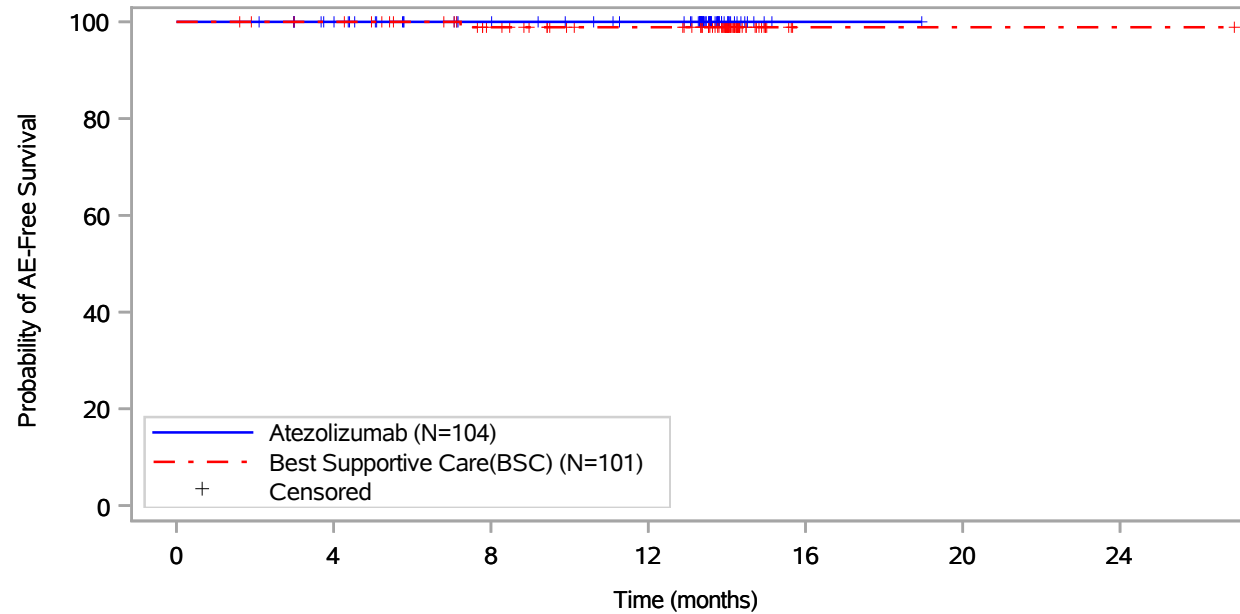
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebellar infarction



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	
Best Supportive Care(BSC) (N=101)	101	98	85	76	1	1	1	
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99	

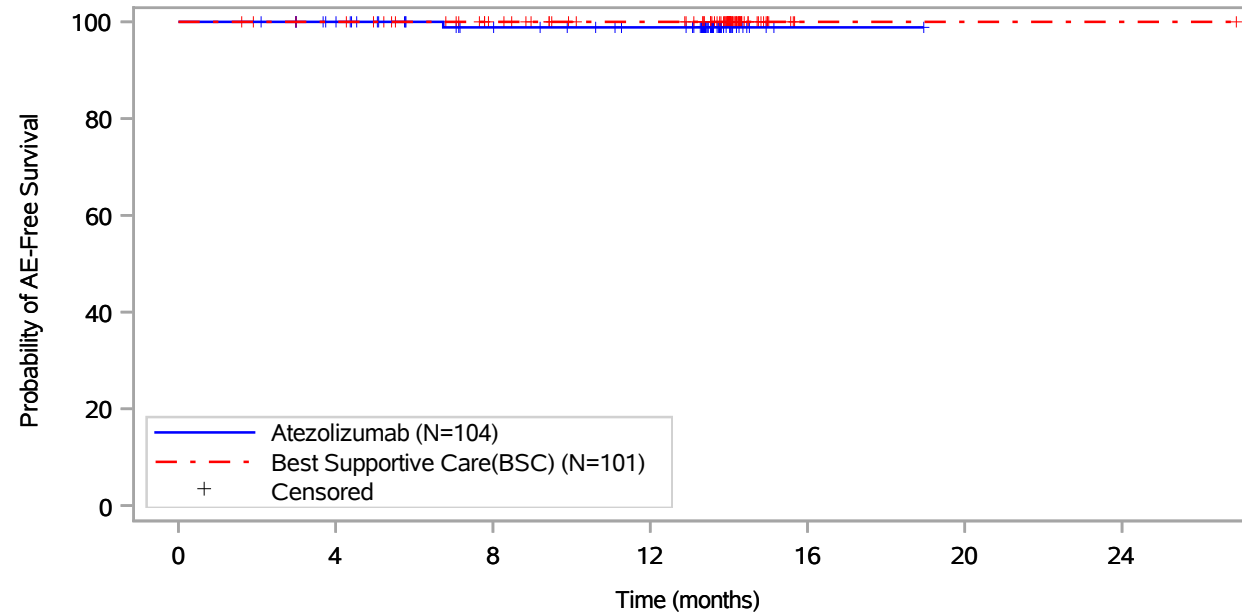
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Nervous system disorders, Cerebral infarction



Patients at risk							
Atezolizumab (N=104)	104	97	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

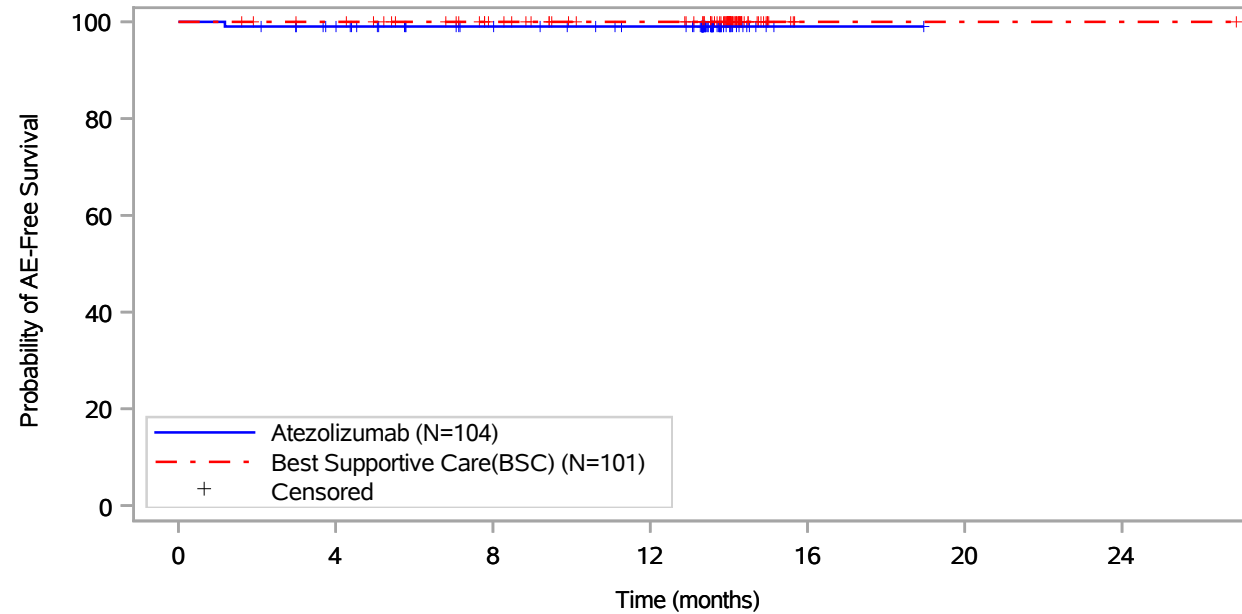
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Nervous system disorders, Demyelinating polyneuropathy



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

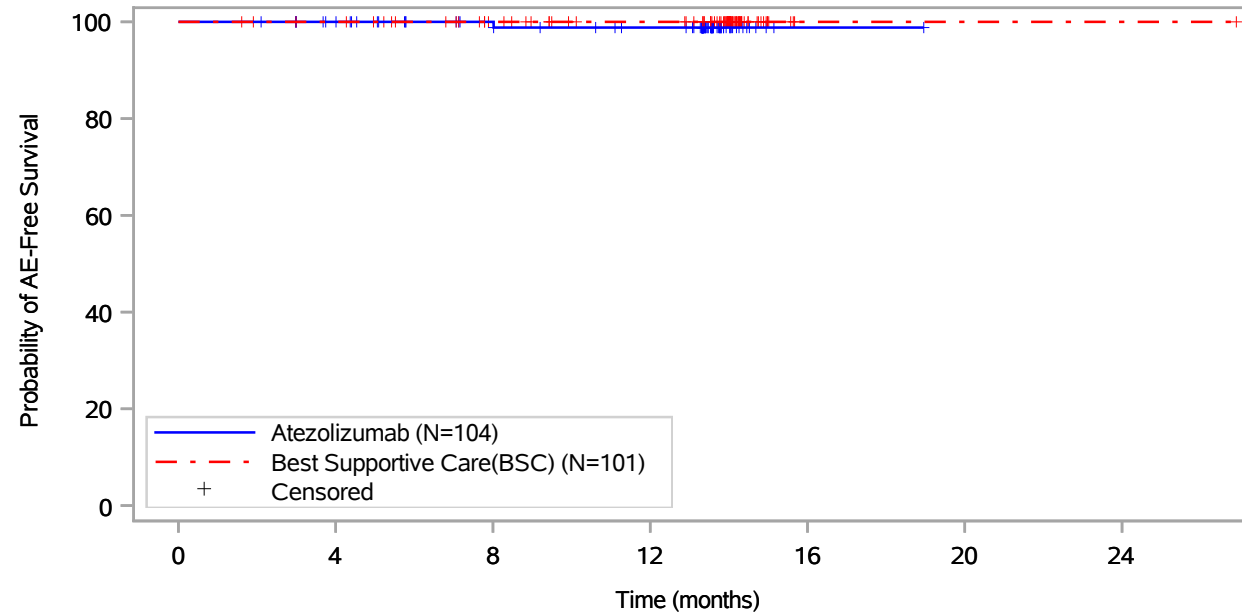
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Nervous system disorders, Loss of consciousness



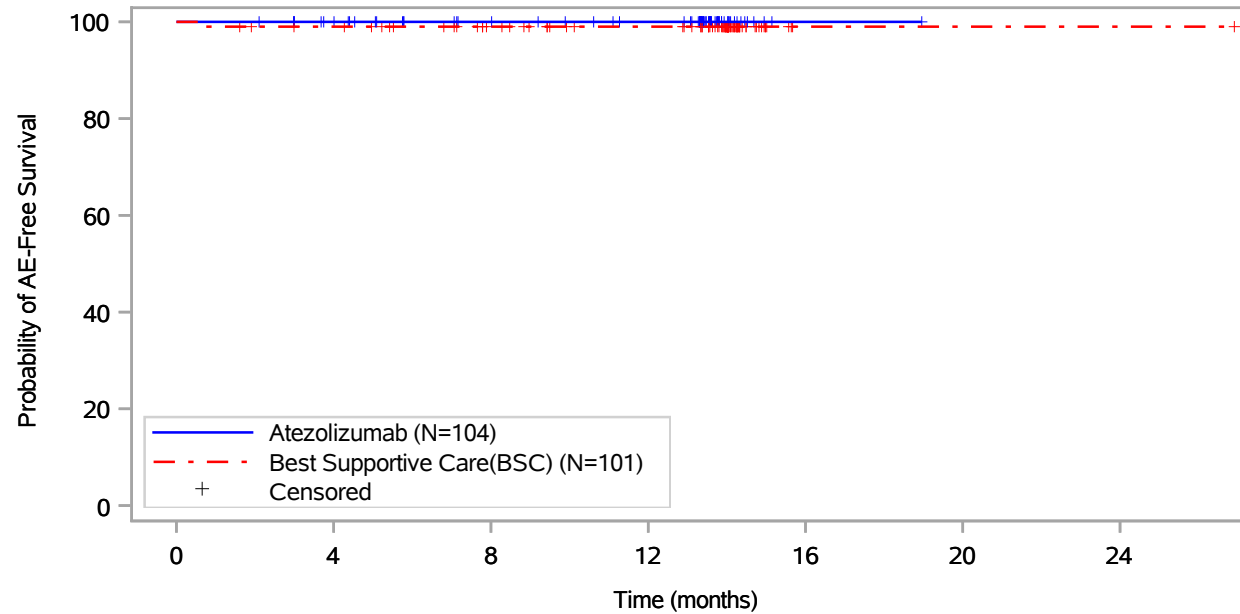
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527
 Nervous system disorders, Paraesthesia



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	85	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

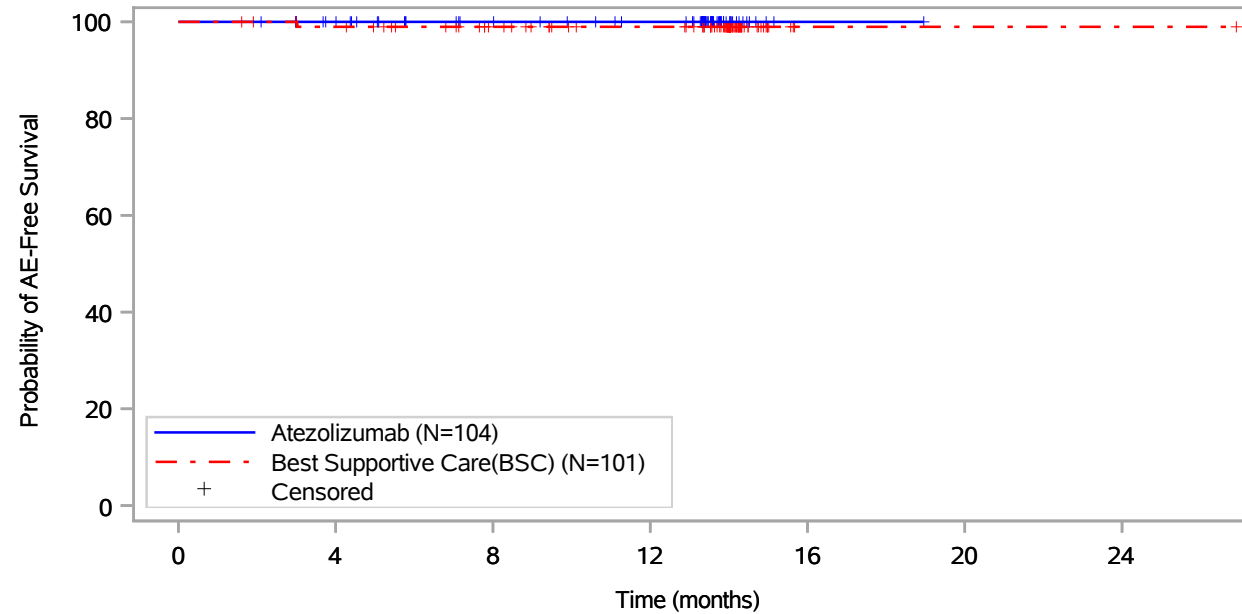
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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Nervous system disorders, Peripheral sensory neuropathy



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	85	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

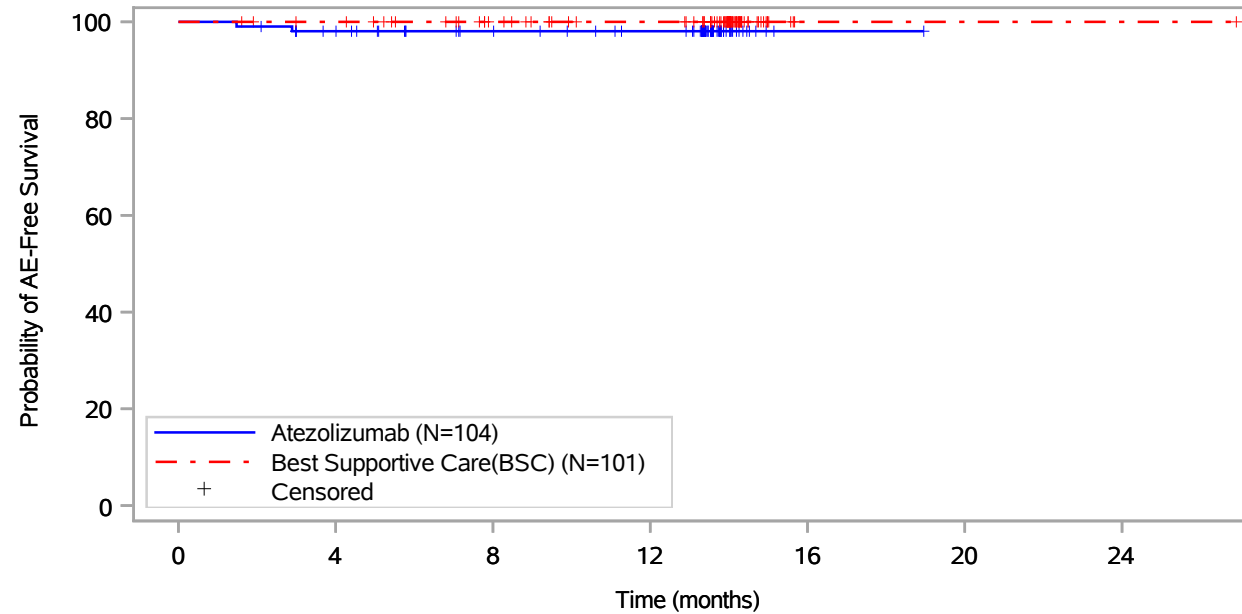
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

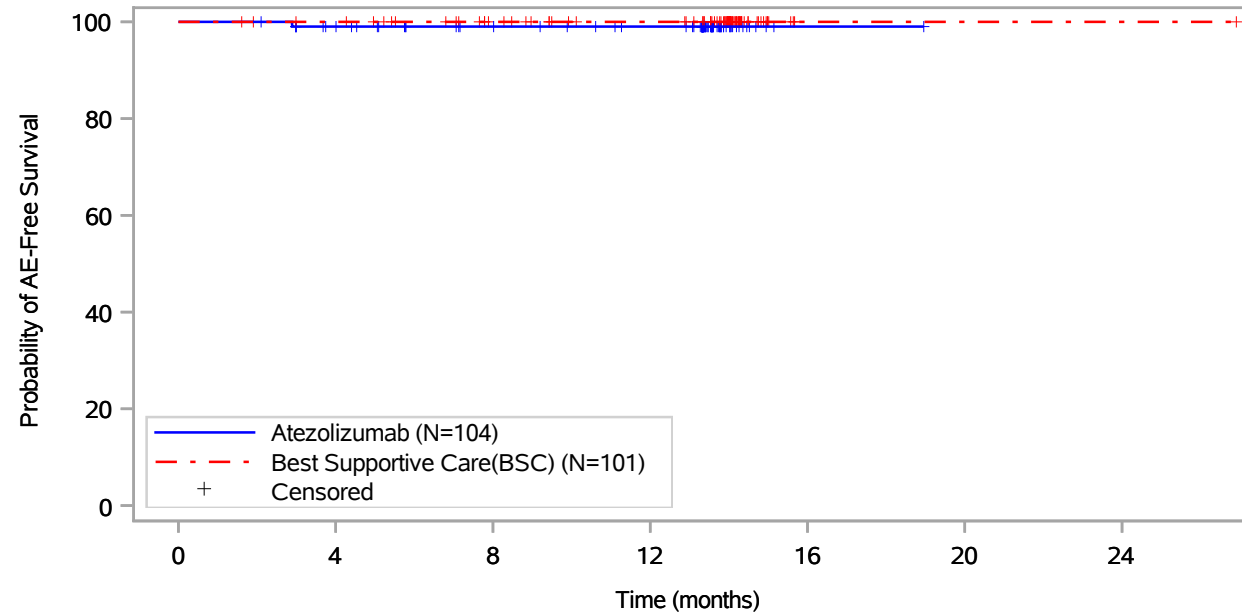
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 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Interstitial lung disease



Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

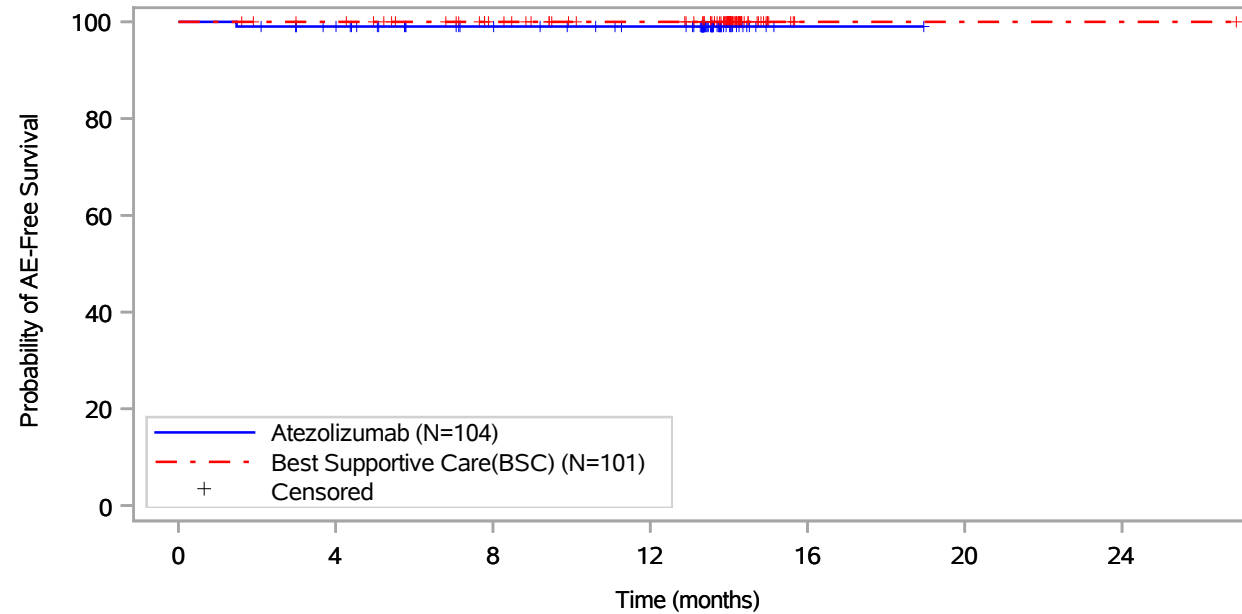
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Pneumonitis



Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

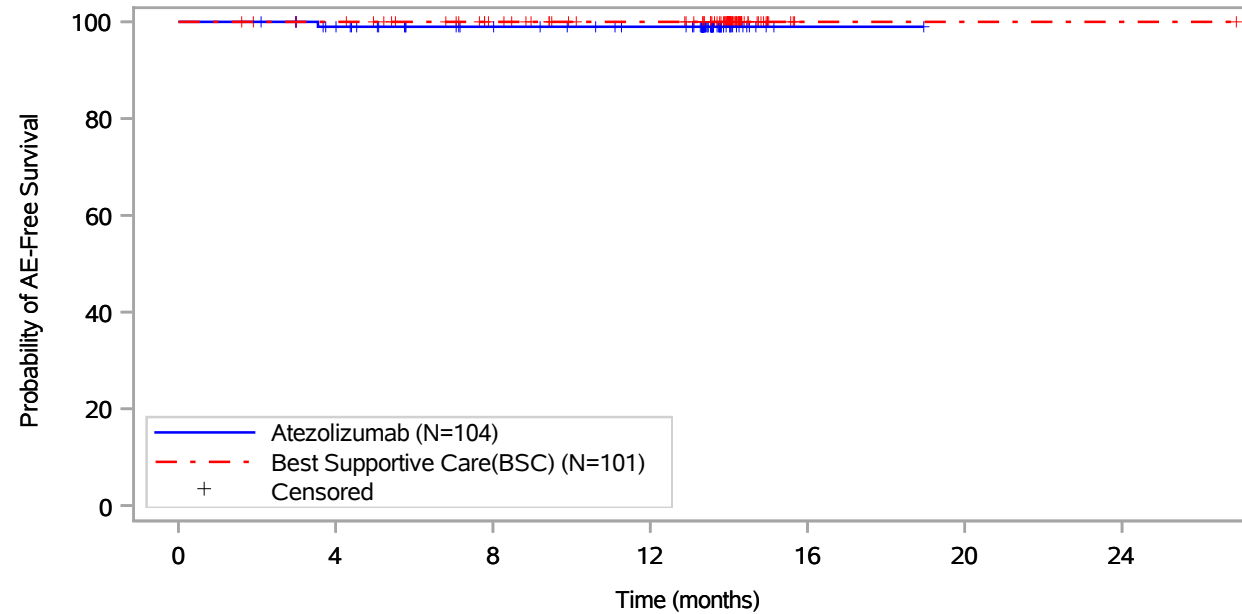
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk							
Atezolizumab (N=104)	104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

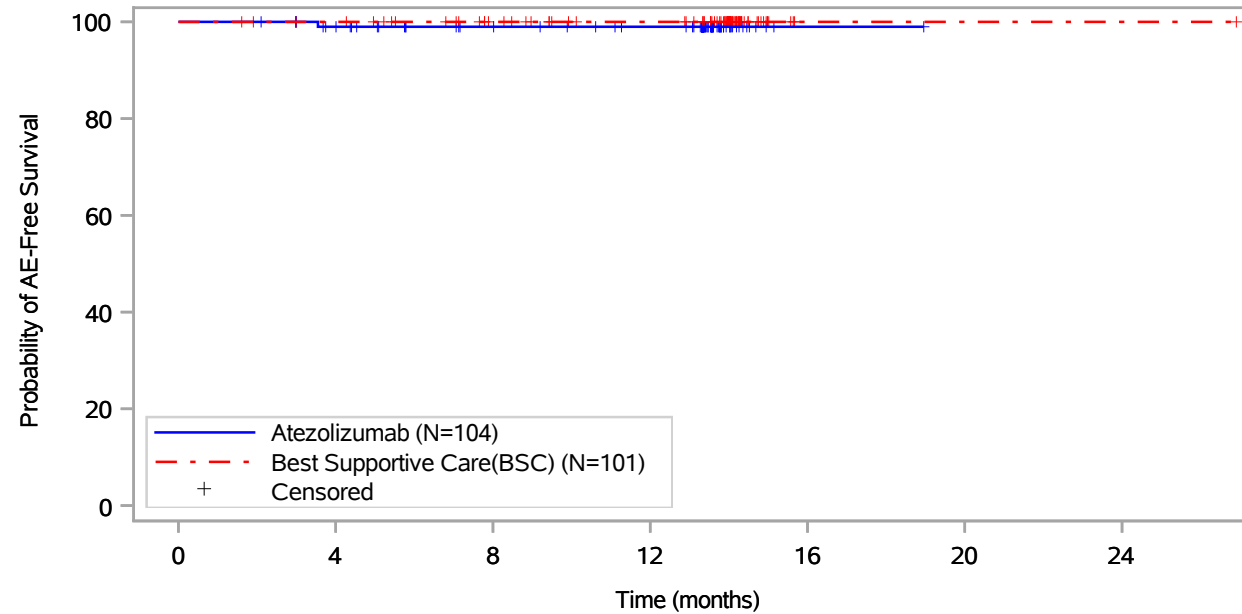
Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, Psoriasis



Patients at risk							
Atezolizumab (N=104)	104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 20:53

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

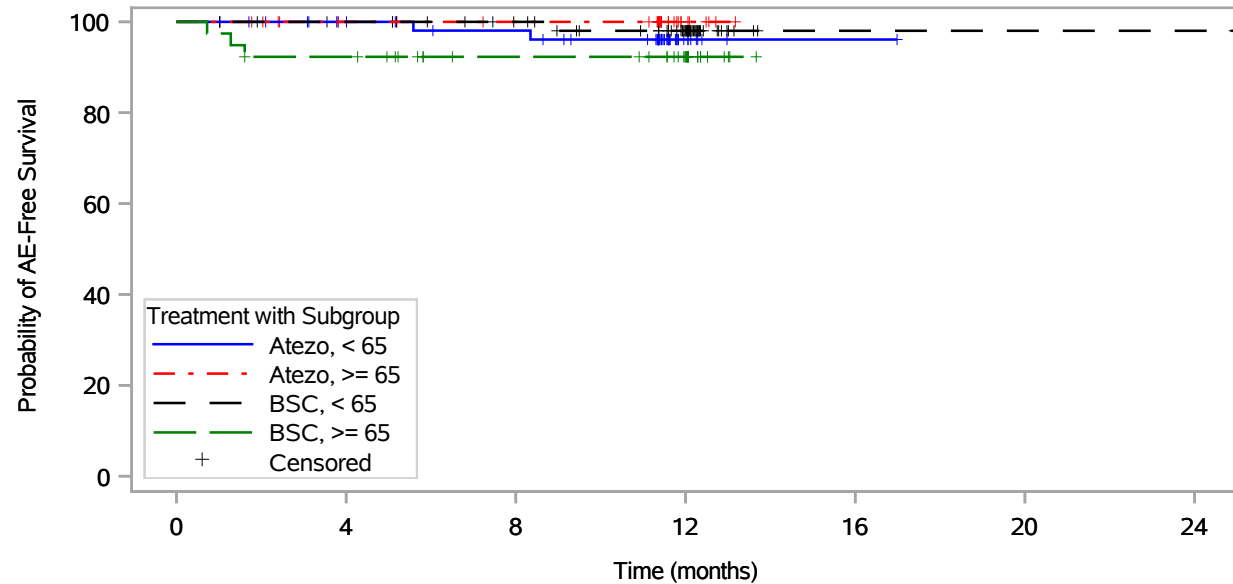
KM Plots

Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Ear and labyrinth disorders, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	55	50	8	1	NE	NE
Atezo, >= 65	40	34	32	6	NE	NE	NE
BSC, < 65	62	59	53	34	1	1	1
BSC, >= 65	39	35	27	18	NE	NE	NE

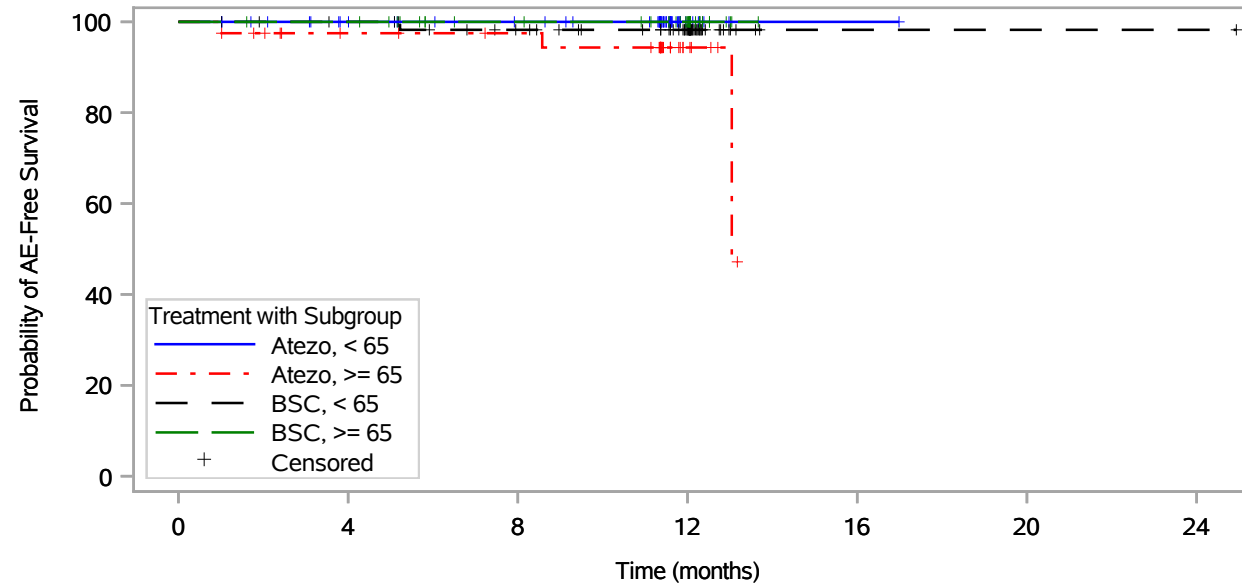
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Infections and infestations, Cystitis (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	55	50	8	1	NE	NE
Atezo, \geq 65	40	33	31	6	NE	NE	NE
BSC, < 65	62	59	52	34	1	1	1
BSC, \geq 65	39	38	30	20	NE	NE	NE

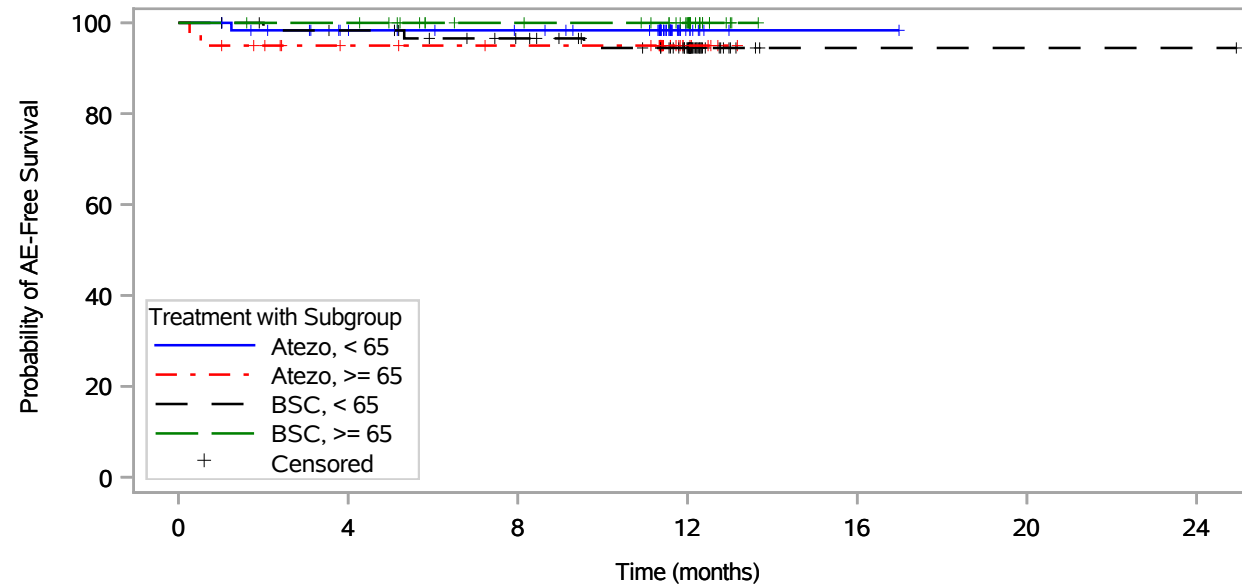
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Infections and infestations, Influenza (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	54	49	8	1	NE	NE
Atezo, >= 65	40	32	30	6	NE	NE	NE
BSC, < 65	62	58	51	33	1	1	1
BSC, >= 65	39	38	30	20	NE	NE	NE

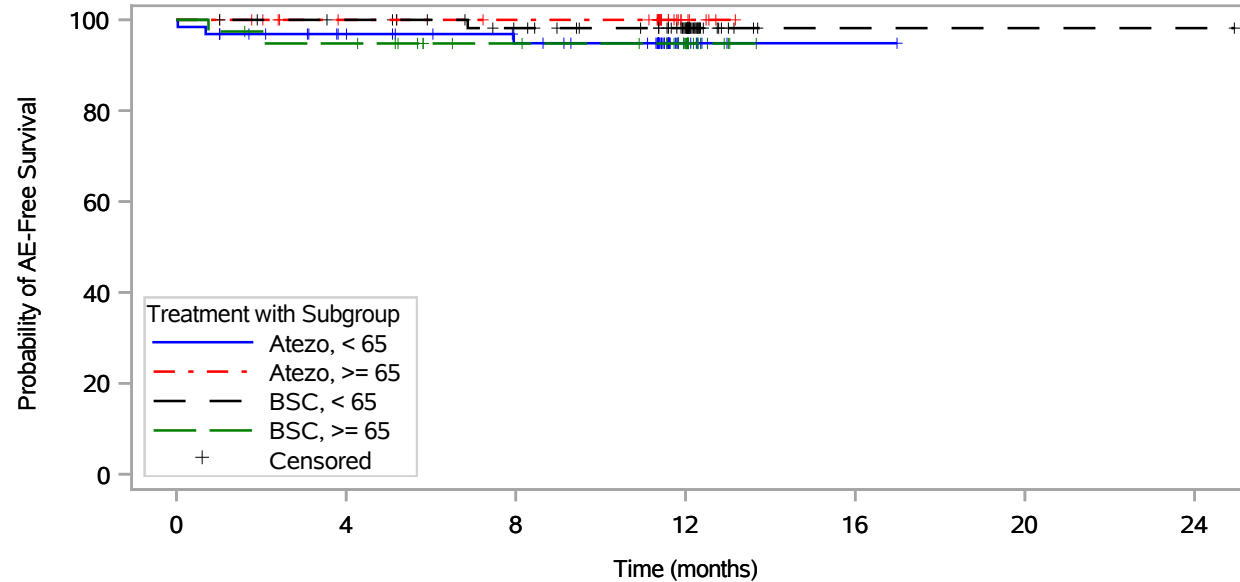
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Infections and infestations, Pharyngitis (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	53	47	8	1	NE	NE
Atezo, >= 65	40	34	32	6	NE	NE	NE
BSC, < 65	62	59	52	34	1	1	1
BSC, >= 65	39	36	29	20	NE	NE	NE

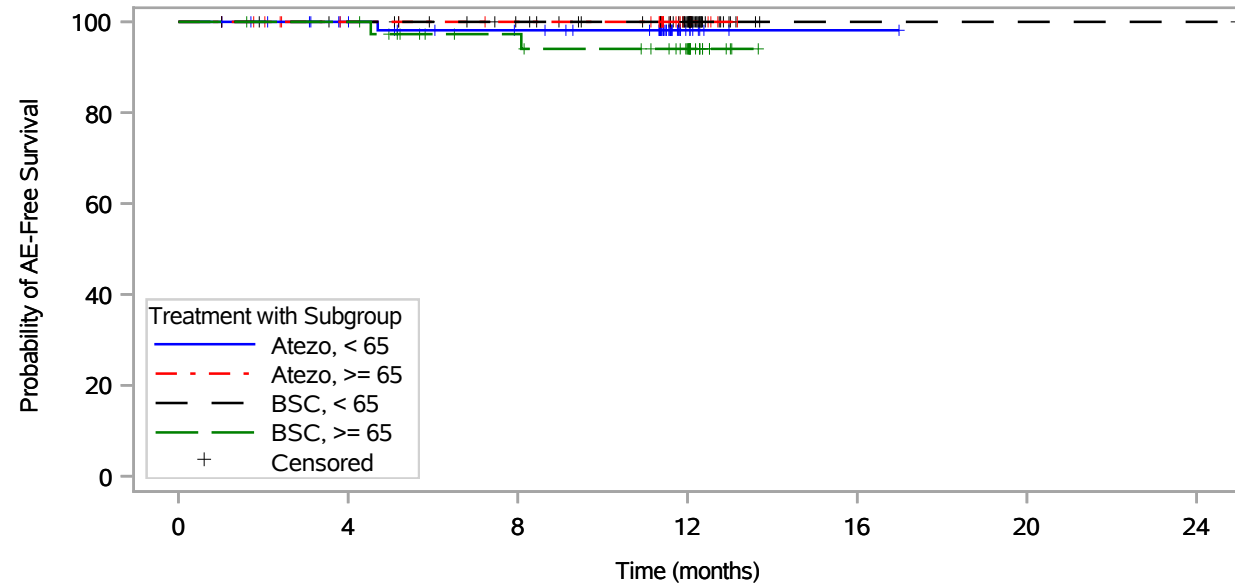
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Infections and infestations, Urinary tract infection (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	55	49	8	1	NE	NE
Atezo, >= 65	40	34	32	6	NE	NE	NE
BSC, < 65	62	59	53	35	1	1	1
BSC, >= 65	39	38	30	20	NE	NE	NE

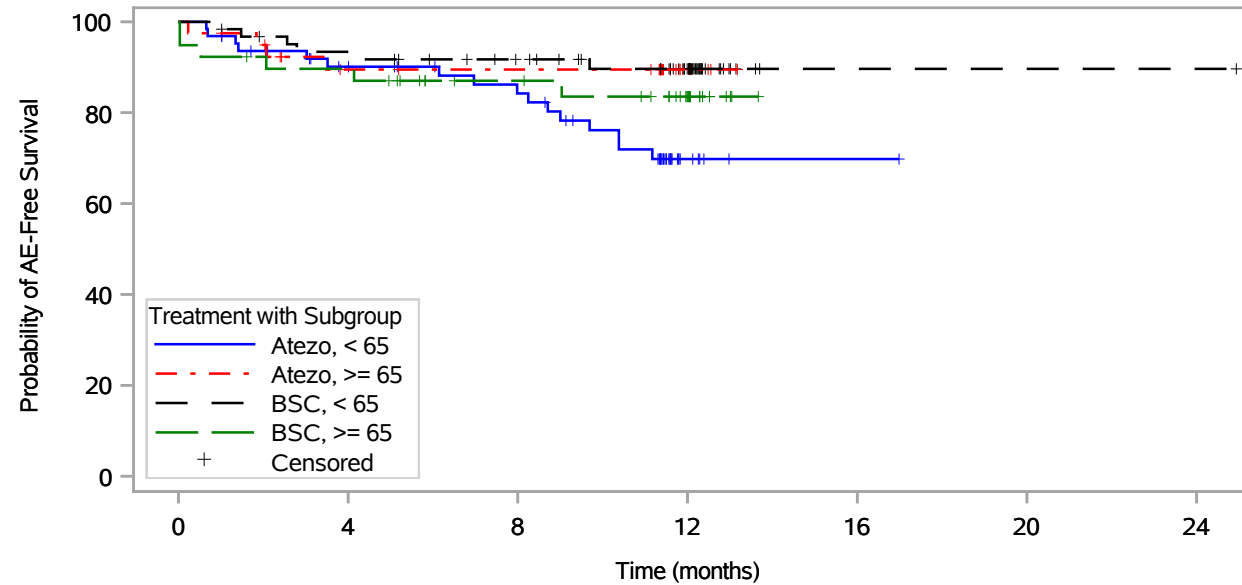
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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 27JUN2022 19:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Metabolism and nutrition disorders, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	50	43	6	1	NE	NE
Atezo, \geq 65	40	31	30	5	NE	NE	NE
BSC, < 65	62	56	49	33	1	1	1
BSC, \geq 65	39	34	26	15	NE	NE	NE

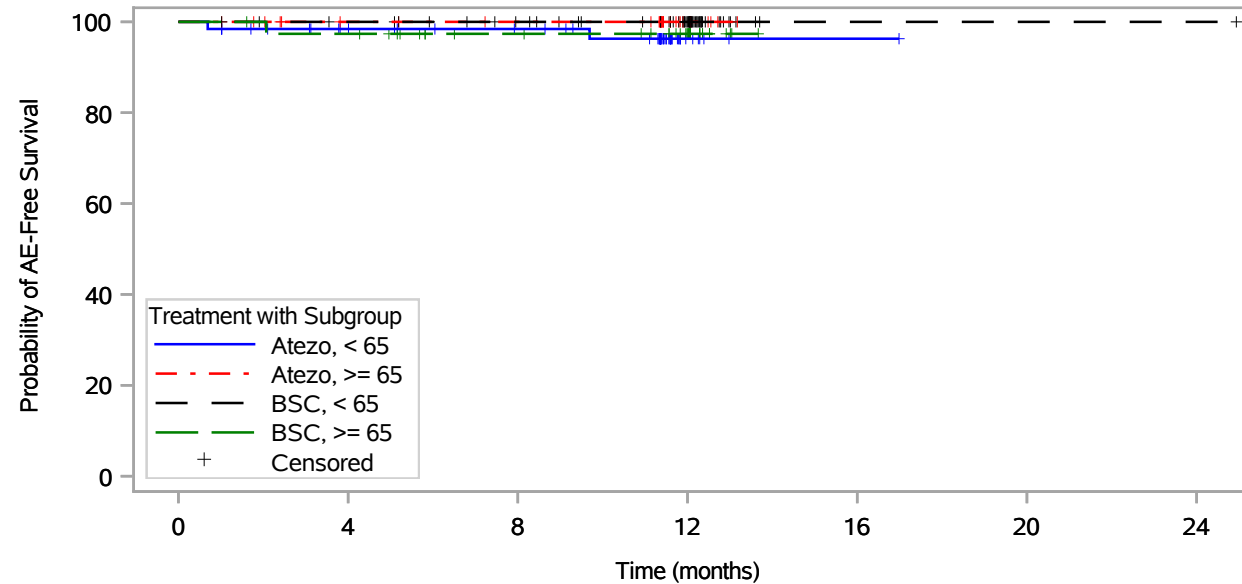
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Age at Randomization; Metabolism and nutrition disorders, Hypertriglyceridaemia (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, < 65	64	54	49	6	1	NE	NE
Atezo, >= 65	40	34	32	6	NE	NE	NE
BSC, < 65	62	59	53	35	1	1	1
BSC, >= 65	39	37	29	19	NE	NE	NE

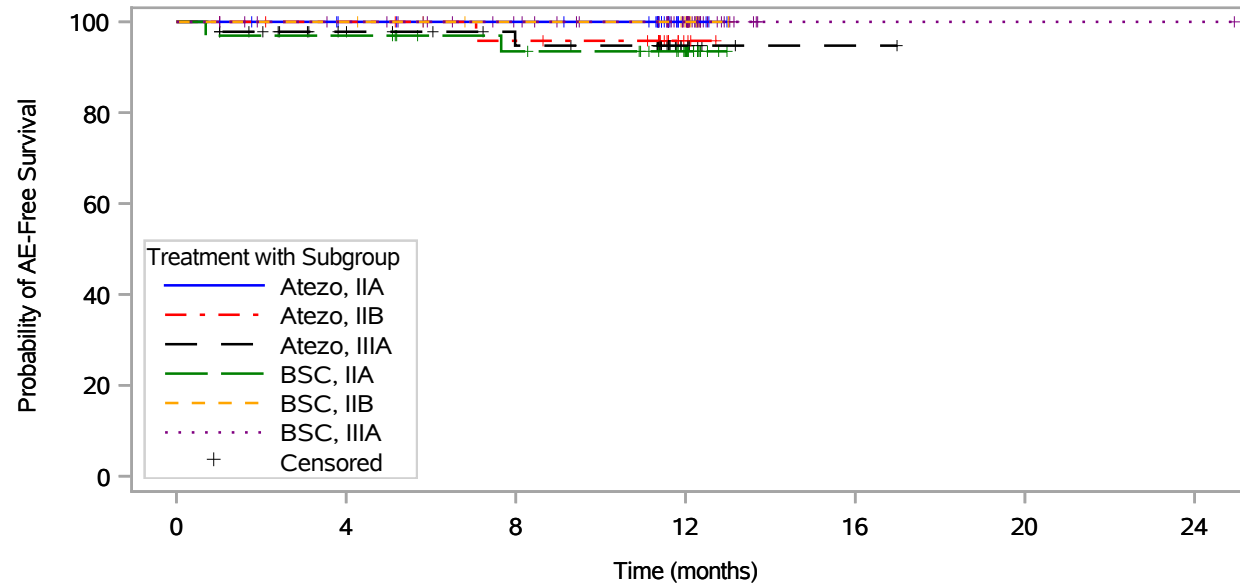
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Tumor stage; General disorders and administration site conditions, Fatigue (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, IIA	31	27	26	4	NE	NE	NE
Atezo, IIB	27	25	23	3	NE	NE	NE
Atezo, IIIA	46	36	31	7	1	NE	NE
BSC, IIA	33	32	27	16	NE	NE	NE
BSC, IIB	15	15	12	10	NE	NE	NE
BSC, IIIA	53	49	42	27	1	1	1

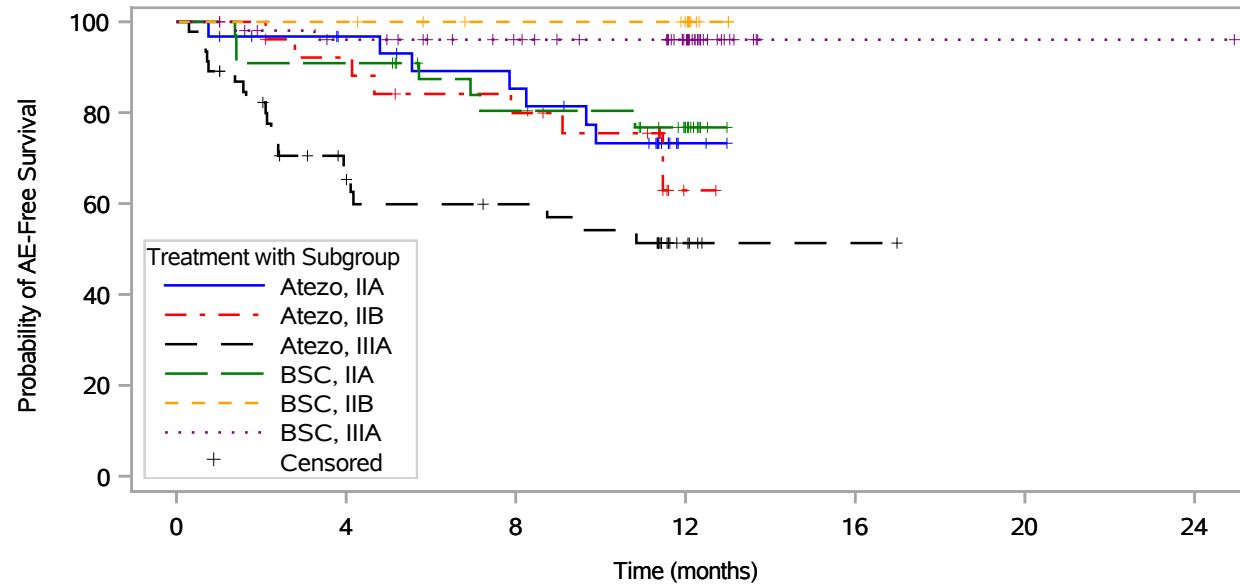
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Tumor stage; Investigations, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, IIA	31	26	22	2	NE	NE	NE
Atezo, IIB	27	23	19	1	NE	NE	NE
Atezo, IIIA	46	25	21	5	1	NE	NE
BSC, IIA	33	30	23	13	NE	NE	NE
BSC, IIB	15	15	12	10	NE	NE	NE
BSC, IIIA	53	47	40	27	1	1	1

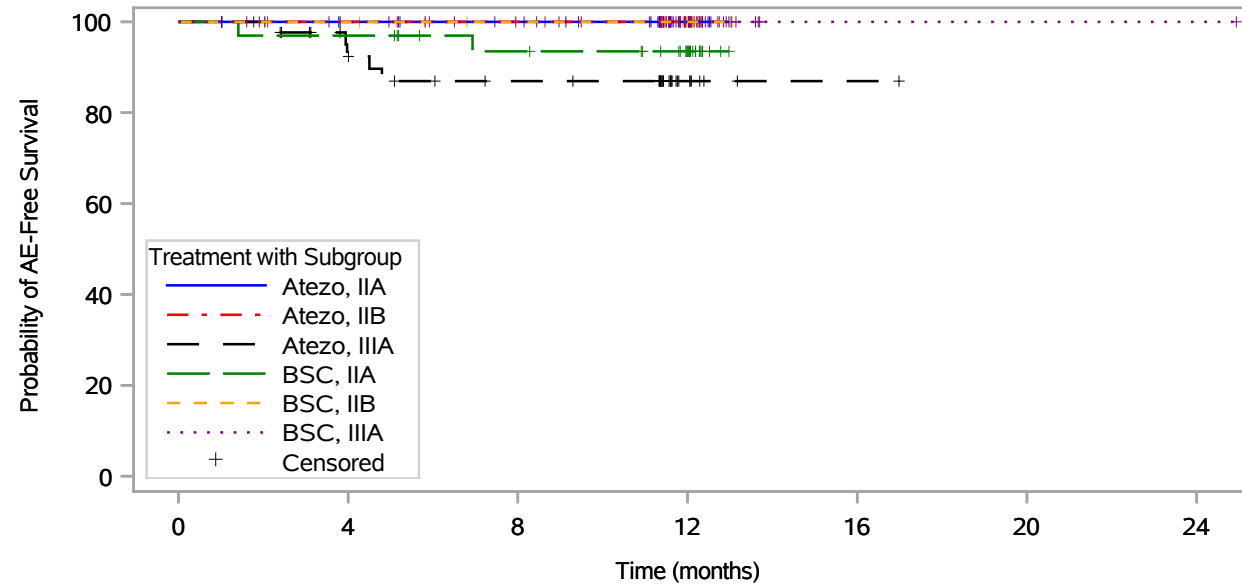
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Tumor stage; Investigations, Weight increased (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, IIA	31	27	26	4	NE	NE	NE
Atezo, IIB	27	25	24	3	NE	NE	NE
Atezo, IIIA	46	35	29	7	1	NE	NE
BSC, IIA	33	32	27	17	NE	NE	NE
BSC, IIB	15	15	12	10	NE	NE	NE
BSC, IIIA	53	49	42	27	1	1	1

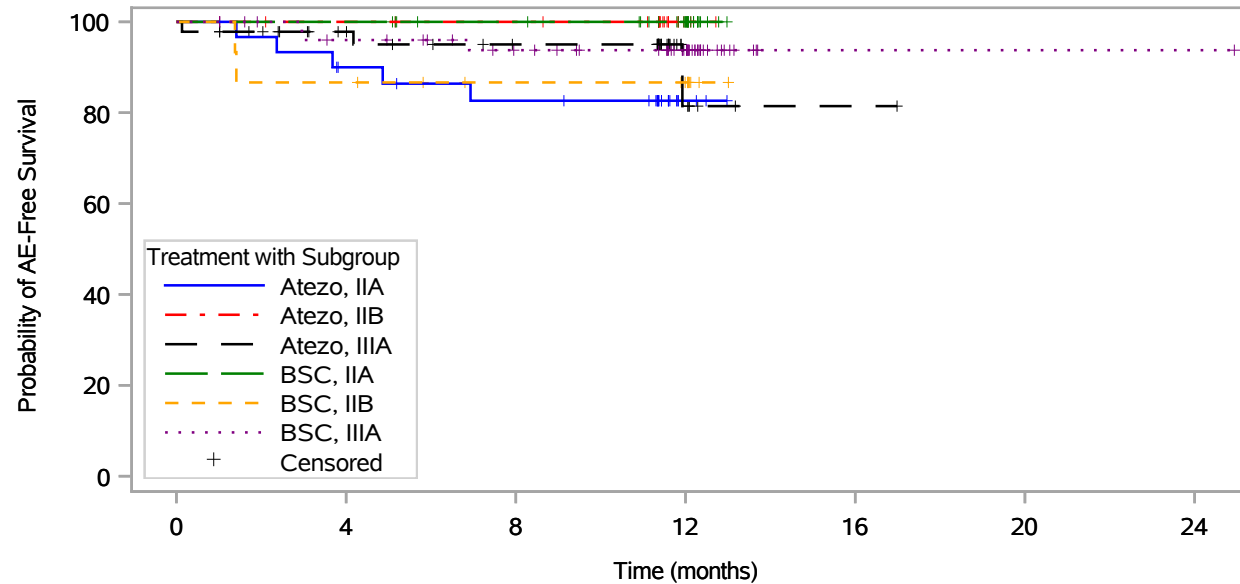
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Tumor stage; Respiratory, thoracic and mediastinal disorders, Dyspnoea (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, IIA	31	25	22	3	NE	NE	NE
Atezo, IIB	27	25	24	3	NE	NE	NE
Atezo, IIIA	46	36	30	6	1	NE	NE
BSC, IIA	33	33	29	18	NE	NE	NE
BSC, IIB	15	13	10	8	NE	NE	NE
BSC, IIIA	53	47	40	26	1	1	1

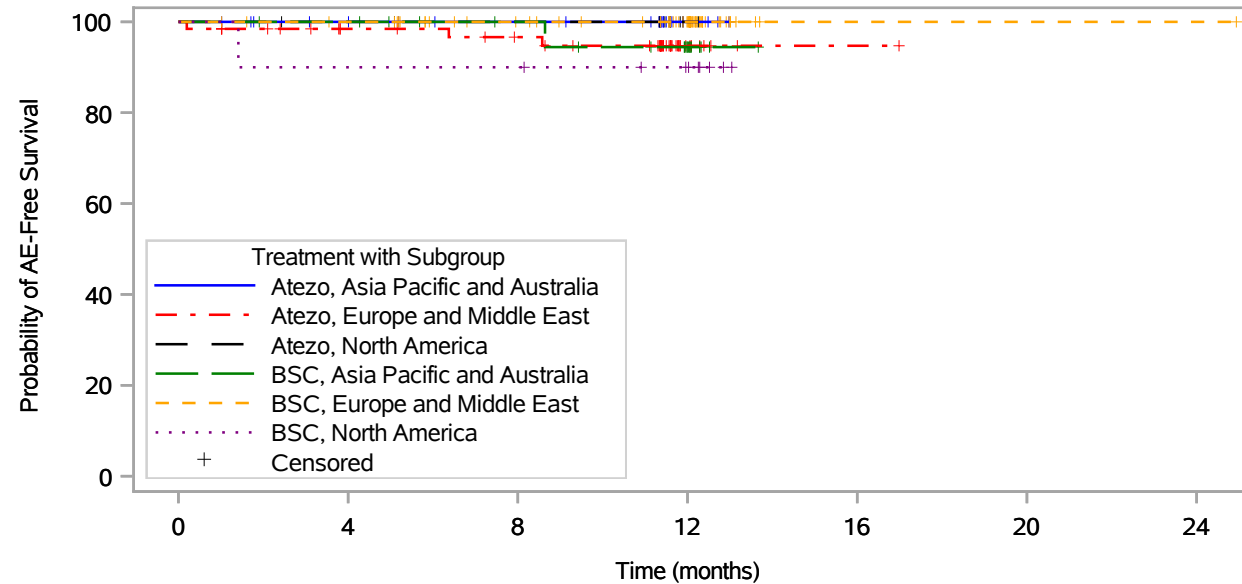
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Geographic Region; Reproductive system and breast disorders, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Asia Pacific and Australia	29	25	22	4	NE	NE	NE
Atezo, Europe and Middle East	65	55	51	7	1	NE	NE
Atezo, North America	10	9	8	2	NE	NE	NE
BSC, Asia Pacific and Australia	23	22	18	10	NE	NE	NE
BSC, Europe and Middle East	68	65	55	38	1	1	1
BSC, North America	10	9	9	6	NE	NE	NE

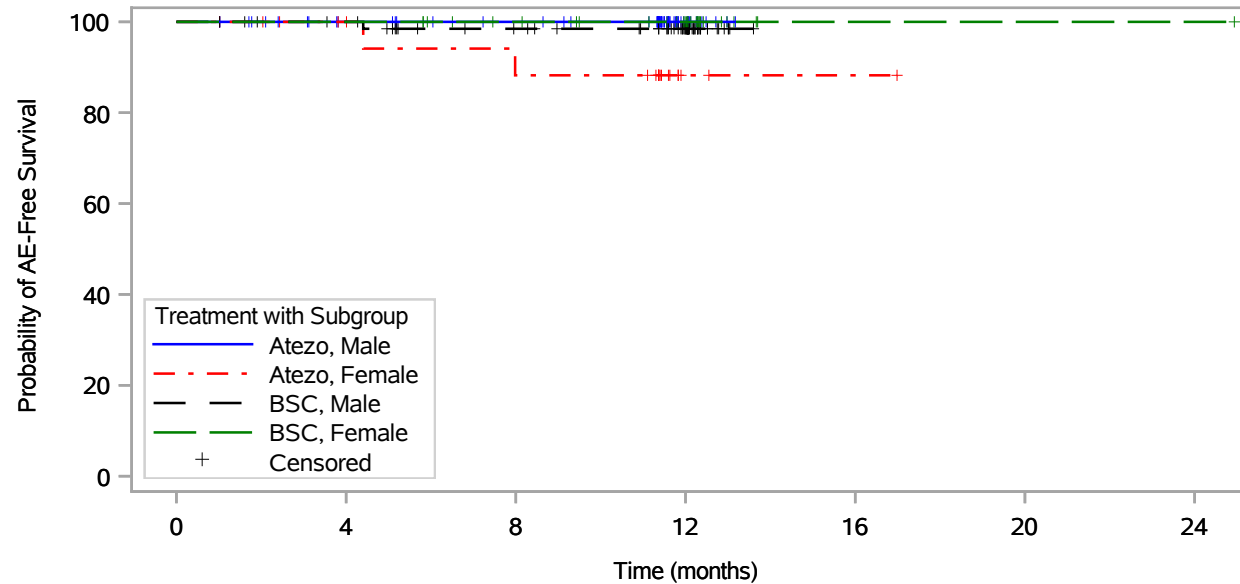
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Gastrointestinal disorders, Vomiting (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Male	82	71	66	12	NE	NE	NE
Atezo, Female	22	18	15	2	1	NE	NE
BSC, Male	71	67	57	37	NE	NE	NE
BSC, Female	30	30	25	17	1	1	1

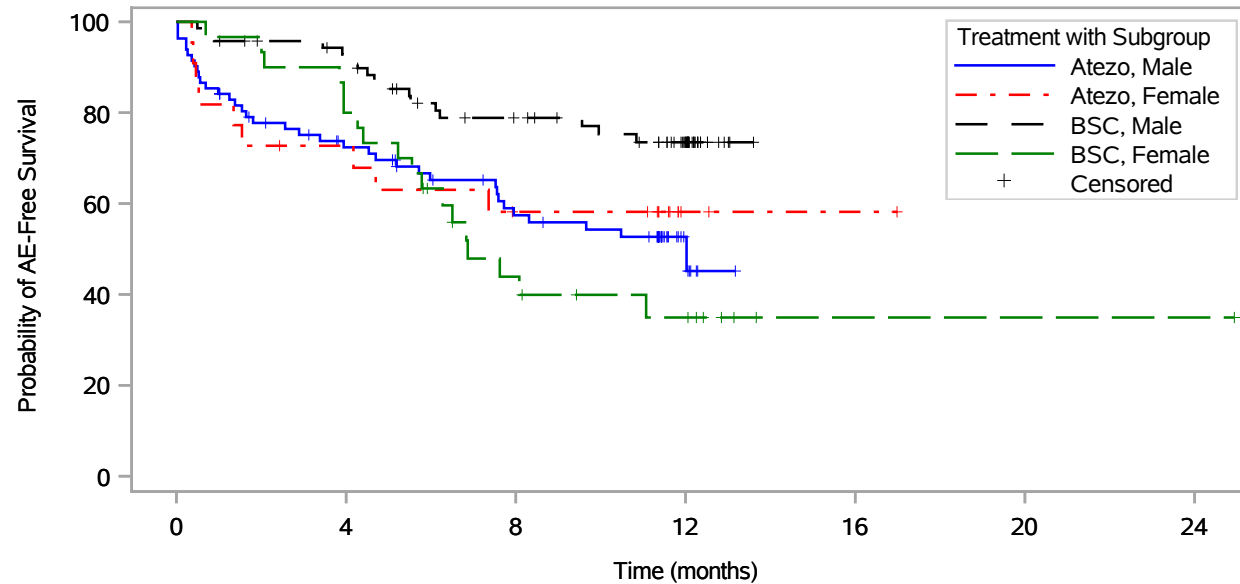
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Infections and infestations, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Male	82	52	37	7	NE	NE	NE
Atezo, Female	22	15	11	2	1	NE	NE
BSC, Male	71	62	47	28	NE	NE	NE
BSC, Female	30	24	11	7	1	1	1

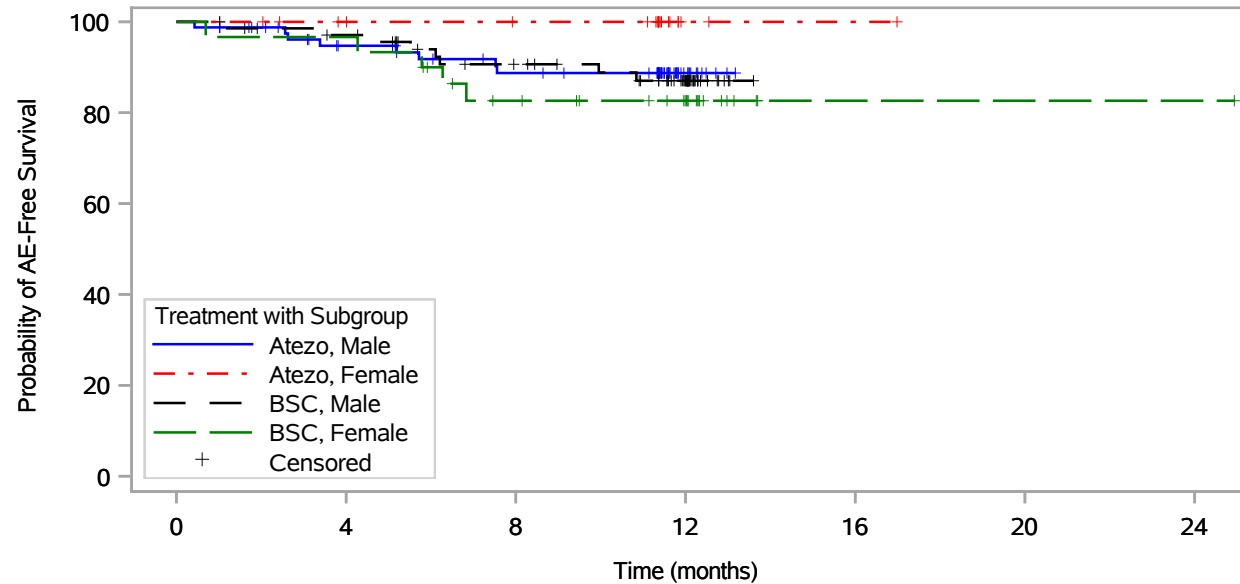
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Infections and infestations, Nasopharyngitis (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Male	82	67	58	11	NE	NE	NE
Atezo, Female	22	18	16	2	1	NE	NE
BSC, Male	71	65	53	33	NE	NE	NE
BSC, Female	30	29	21	14	1	1	1

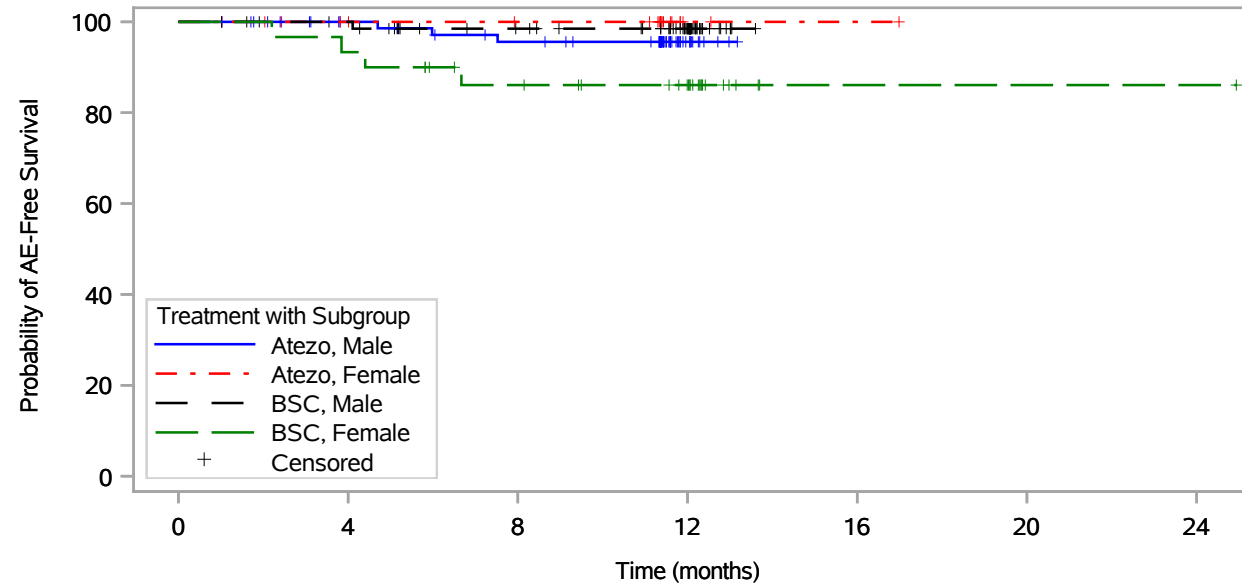
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Infections and infestations, Upper respiratory tract infection (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Male	82	71	63	11	NE	NE	NE
Atezo, Female	22	18	16	2	1	NE	NE
BSC, Male	71	67	57	37	NE	NE	NE
BSC, Female	30	28	22	16	1	1	1

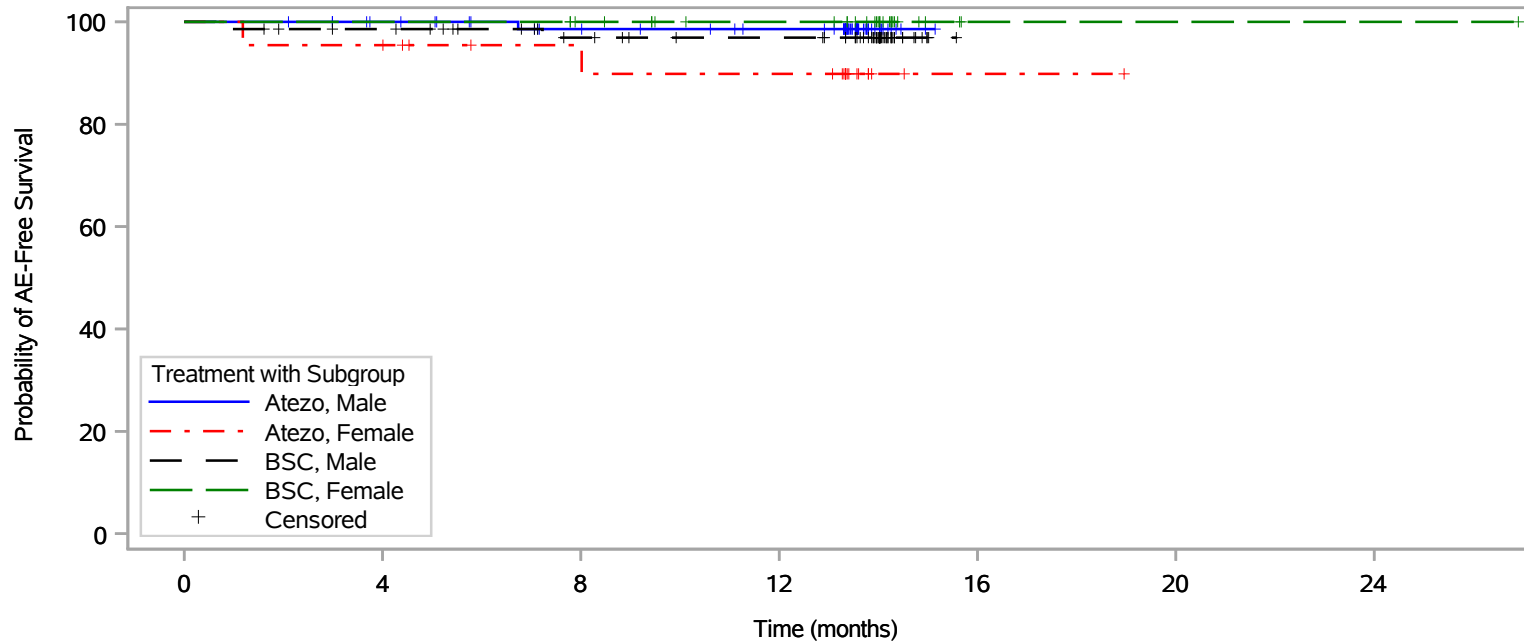
Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Serious Adverse Event
STUDY: GO29527

Sex; Nervous system disorders, All (N=205)



Patients at risk	0	4	8	12	16	20	24
Atezo, Male	82	76	67	62	NE	NE	NE
Atezo, Female	22	21	17	16	1	NE	NE
BSC, Male	71	67	57	53	NE	NE	NE
BSC, Female	30	30	27	22	1	1	1

Atezo = Atezolizumab, BSC = Best Supportive Care. Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Spezifische Verträglichkeit

Operationalisierung der Adverse Events of Special Interest (AESI)

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Rash	Sponsor defined AEGT	Atezo immune-mediate rash CURRENT AEGT consisting of the following PTs: Acne, Acne cystic, Acne fulminans, Acne pustular, Acquired epidermolysis bullosa, Administration site vesicles, Anal blister, Application site acne, Application site vesicles, Autoimmune blistering disease, Benign familial pemphigus, Blister, Blister rupture, Blood blister, Bullous erysipelas, Bullous haemorrhagic dermatosis, Bullous impetigo, Butterfly rash, Catheter site vesicles, Cervical bulla, Coma blister, Dermatitis, Dermatitis acneiform, Dermatitis allergic, Dermatitis herpetiformis, Dermatitis infected, Diabetic bullosis, Drug eruption, Eczema, Eczema infected, Eczema vesicular, Eczema weeping, Epidermal necrosis, Epidermolysis, Epidermolysis bullosa, Erythema, Erythema of eyelid, Eyelid folliculitis, Eyelid rash, Fixed eruption, Folliculitis, Fracture blisters, Furuncle, Genital blister, Hand dermatitis, Herpes gestationis, Immune-mediated dermatitis, Implant site vesicles, Incision site vesicles, Infusion site vesicles, Injection site vesicles, Instillation site vesicles, Linear IgA disease, Lip blister, Medical device site vesicles, Mucocutaneous rash, Mucosa vesicle, Nodular rash, Ocular pemphigoid, Oedema blister, Oral blood blister, Palmar-plantar erythrodysesthesia syndrome, Paraneoplastic pemphigus, Pemphigoid, Pemphigus, Penile blister, Porphyria non-acute, PRIDE syndrome, Pseudoporphyria, Pseudosyndactyly, Rash, Rash erythematous, Rash follicular, Rash macular, Rash maculo-papular, Rash maculovesicular, Rash morbilliform, Rash papular, Rash papulosquamous, Rash pruritic, Rash pustular, Rash rubelliform, Rash scarlatiniform, Rash vesicular, Scrotal dermatitis, Seborrhoeic dermatitis, Skin exfoliation, Skin toxicity, Skin ulcer, Staphylococcal scalded skin syndrome, Symmetrical drug-related intertriginous and flexural exanthema, Toxic erythema of chemotherapy, Urticarial dermatitis, Vaccination site vesicles, Vascular access site rash, Vascular access site vesicles, Vasculitic rash, Vessel puncture site vesicles, Vulvovaginal exfoliation
Immune-Mediated Hepatitis	SMQ	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) narrow
	SMQ	Hepatitis, non-infectious (SMQ) narrow
	SMQ	Liver related investigations, signs and symptoms (SMQ) narrow
Immune-Mediated Hypothyroidism	SMQ	Hypothyroidism (SMQ) wide
Immune-Mediated Hyperthyroidism	SMQ	Hyperthyroidism (SMQ) narrow
Immune-Mediated Pneumonitis	SMQ	Interstitial lung disease (SMQ) narrow
Immune-Mediated Severe Cutaneous Reaction	SMQ	Severe cutaneous adverse reactions (SMQ) narrow
Immune-Mediated Meningoencephalitis	SMQ	Noninfectious meningitis (SMQ) narrow
	SMQ	Noninfectious encephalitis (SMQ) narrow
Immune-Mediated Meningitis	SMQ	Noninfectious meningitis (SMQ) narrow
Immune-Mediated Encephalitis	SMQ	Noninfectious encephalitis (SMQ) narrow
Immune-Mediated Colitis	HLT	Colitis (excl infective)

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Guillain-Barre	SMQ	Guillain-Barre syndrome (SMQ) narrow
Immune-Mediated Ocular Inflammatory Toxicity	Sponsor defined AEGT	Atezolizumab Ocular Inflammation Toxicity AEGT consisting of the following PTs: Anterior chamber inflammation, Atopic keratoconjunctivitis, Autoimmune eye disorder, Autoimmune retinopathy, Autoimmune uveitis, Chorioretinitis, Chorioretinopathy, Choroidal detachment, Choroiditis, Corneal endotheliitis, Detachment of macular retinal pigment epithelium, Detachment of retinal pigment epithelium, Diffuse lamellar keratitis, Episcleritis, Eye inflammation, Immune recovery uveitis, Immune-mediated uveitis, Iridocyclitis, Iritis, Keratitis, Keratitis interstitial, Necrotising retinitis, Necrotising scleritis, Non-infectious endophthalmitis, Noninfective chorioretinitis, Noninfective conjunctivitis, Noninfective retinitis, Ocular pemphigoid, Ocular vasculitis, Optic neuritis, Optic neuropathy, Optic perineuritis, Papillitis, Punctate keratitis, Retinal detachment, Retinal vasculitis, Retinitis, Retinopathy, Retinoschisis, Rheumatoid scleritis, Scleritis, Serpiginous choroiditis, Superior limbic keratoconjunctivitis, Ulcerative keratitis, Uveitis, Vitritis
Autoimmune Hemolytic Anaemia	SMQ	Haemolytic disorders (SMQ) narrow
Immune-Mediated Adrenal Insufficiency	Sponsor defined AEGT	Atezolizumab comprehensive adrenal insufficiency search AEGT consisting of the following PTs: ACTH stimulation test abnormal, Addison's disease, Adrenal androgen deficiency, Adrenal atrophy, Adrenal insufficiency, Adrenal insufficiency neonatal, Adrenal suppression, Adrenalitis, Adrenocortical insufficiency acute, Adrenocortical insufficiency neonatal, Adrenocorticotrophic hormone deficiency, Adrenogenital syndrome, Aldosterone urine abnormal, Aldosterone urine decreased, Apituitarism, Biopsy adrenal gland abnormal, Blood aldosterone abnormal, Blood aldosterone decreased, Blood corticosterone abnormal, Blood corticosterone decreased, Blood corticotrophin abnormal, Blood corticotrophin decreased, Blood corticotrophin increased, Corticotropin-releasing hormone stimulation test, Cortisol decreased, Cortisol free urine decreased, Dexamethasone suppression test, Dexamethasone suppression test positive, Glucocorticoid deficiency, Glucocorticoids abnormal, Glucocorticoids decreased, Hydroxycorticosteroids urine abnormal, Hydroxycorticosteroids urine decreased, Hypoaldosteronism, Hypothalamic pituitary adrenal axis suppression, Mineralocorticoid deficiency, Primary adrenal insufficiency, Scan adrenal gland abnormal, Secondary adrenocortical insufficiency, Steroid withdrawal syndrome, Triple A syndrome, Urine cortisol/creatinine ratio abnormal, Urine cortisol/creatinine ratio decreased
Immune-Mediated Diabetes Mellitus	Sponsor defined AEGT	Atezolizumab Diabetes/DKA (excludes hyperglycemia) AEGT consisting of the following MedDRA PTs: Diabetes mellitus, Diabetic coma, Diabetic hyperglycaemic coma, Diabetic ketoacidosis, Diabetic ketoacidotic hyperglycaemic coma, Fulminant type 1 diabetes mellitus, Ketoacidosis, Latent autoimmune diabetes in adults, Type 1 diabetes mellitus
Immune-Mediated Hypophysitis	HLT	Hypothalamic and pituitary disorders NEC
Immune-Mediated Myasthenia Gravis	HLT	Myasthenia gravis and related conditions
Immune-Mediated Myocarditis	Sponsor defined AEGT	Atezolizumab Myocarditis Immune-Mediated AEGT consisting of the following PTs: Autoimmune myocarditis, Eosinophilic myocarditis, Giant cell myocarditis, Hypersensitivity myocarditis, Immune-mediated myocarditis, Myocarditis

Vollständige Darstellung relevanter Ergebnisse

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Myositis	HLT	Muscle infections and inflammations
	HLT	Muscular autoimmune disorders
Immune-Mediated Nephritis	HLT	Glomerulonephritis and nephrotic syndrome
	HLT	Nephritis NEC
Immune-Mediated Pancreatitis	Sponsor defined AEGT	Atezolizumab pancreatitis AEGT consisting of the the following MedDRA PTs: Amylase abnormal, Amylase increased, Autoimmune pancreatitis, Cullen's sign, Grey Turner's sign, Haemorrhagic necrotic pancreatitis, Hereditary pancreatitis, Ischaemic pancreatitis, Lipase abnormal, Lipase increased, Oedematous pancreatitis, Pancreatic abscess, Pancreatic enzyme abnormality, Pancreatic enzymes abnormal, Pancreatic enzymes increased, Pancreatic haemorrhage, Pancreatic necrosis, Pancreatic phlegmon, Pancreatic pseudocyst, Pancreatic pseudocyst drainage, Pancreatitis, Pancreatitis acute, Pancreatitis haemorrhagic, Pancreatitis necrotising, Pancreatitis relapsing, Pancreatorenal syndrome, Subacute pancreatitis
Immune-Mediated Vasculitis	SMQ	Vasculitis (SMQ) narrow
Infusion-Related Reaction	PT	Infusion Related Reaction (Only include if occurred on same day or within 1 day of atezolizumab infusion)
	PT	Cytokine release syndrome (Only include if occurred on same day or within 1 day of atezolizumab infusion)
Rhabdomyolysis	SMQ	Rhabdomyolysis/myopathy (SMQ) narrow

AEGT = Adverse Event Group Term; AESI = adverse event of special interest; EGFR = epidermal growth factor receptor; HLT = High Level Term; MedDRA = Medical Dictionary for Regulatory Activities; NEC = not elsewhere classified; PT = Preferred Term; SMQ = Standardized MedDRA Query.

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Spezifische Verträglichkeit

Time-to-Event (TTE) Analysen

Unstratifiziert + Subgruppen

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Interaction Test	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	19	18,3	85	81,7	101	100,0	1	1,0	100	99,0	<.0001	20,54	2,75	153,44	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	14	17,1	68	82,9	71	70,3	1	1,4	70	98,6	0,0012	13,19	1,73	100,32	Convergence criterion (GCONV=1E-8) satisfied.	0,3359
	Female	22	21,2	5	22,7	17	77,3	30	29,7	0	0,0	30	100,0	0,0060	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	9	14,1	55	85,9	62	61,4	0	0,0	62	100,0	0,0020	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,2781
	>= 65	40	38,5	10	25,0	30	75,0	39	38,6	1	2,6	38	97,4	0,0039	11,10	1,42	86,73	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	0	0,0	23	100,0	0,0215	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4943
	Europe and Middle East	65	62,5	9	13,8	56	86,2	68	67,3	1	1,5	67	98,5	0,0071	9,95	1,26	78,58	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	4	40,0	6	60,0	10	9,9	0	0,0	10	100,0	0,0201	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	6	19,4	25	80,6	33	32,7	0	0,0	33	100,0	0,0080	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,5940
	IIB	27	26,0	3	11,1	24	88,9	15	14,9	0	0,0	15	100,0	0,1918	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	10	21,7	36	78,3	53	52,5	1	1,9	52	98,1	0,0015	13,09	1,67	102,32	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMRH_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMRH35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Rash Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMRHS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:39

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	16	15,4	88	84,6	101	100,0	0	0	101	100,0	<.0001	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	15	18,3	67	81,7	71	70,3	0	0	71	100,0	0,0002	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	0,9979
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2320	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	10	15,6	54	84,4	62	61,4	0	0	62	100,0	0,0011	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	0,9979
	>= 65	40	38,5	6	15,0	34	85,0	39	38,6	0	0	39	100,0	0,0111	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	3	10,3	26	89,7	23	22,8	0	0	23	100,0	0,1175	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	0	0	68	100,0	0,0004	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
	North America	10	9,6	2	20,0	8	80,0	10	9,9	0	0	10	100,0	0,1464	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	6	19,4	25	80,6	33	32,7	0	0	33	100,0	0,0072	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	1,0000
	IIB	27	26,0	6	22,2	21	77,8	15	14,9	0	0	15	100,0	0,0533	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	
	IIIA	46	44,2	4	8,7	42	91,3	53	52,5	0	0	53	100,0	0,0273	>999.99	0,00	NE	Convergence criterion (GCON=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MLT_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism Grade >= 3
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MLT35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypothyroidism Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMITS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (Likelihood ratio)
All	n/a	104	100,0	14	13,5	90	86,5	101	100,0	5	5,0	96	95,0	0,0342	2,87	1,03	7,97	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	12	14,6	70	85,4	71	70,3	4	5,6	67	94,4	0,0703	2,73	0,88	8,46	Convergence criterion (GCONV=1E-8) satisfied.	0,9572
	Female	22	21,2	2	9,1	20	90,9	30	29,7	1	3,3	29	96,7	0,4086	2,65	0,24	29,19	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	10	15,6	54	84,4	62	61,4	5	8,1	57	91,9	0,1728	2,08	0,71	6,08	Convergence criterion (GCONV=1E-8) satisfied.	0,0972
	>= 65	40	38,5	4	10,0	36	90,0	39	38,6	0	0,0	39	100,0	0,0461	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	6	20,7	23	79,3	23	22,8	2	8,7	21	91,3	0,2126	2,67	0,54	13,29	Convergence criterion (GCONV=1E-8) satisfied.	0,7029
	Europe and Middle East	65	62,5	7	10,8	58	89,2	68	67,3	3	4,4	65	95,6	0,1695	2,50	0,65	9,66	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	1	10,0	9	90,0	10	9,9	0	0,0	10	100,0	0,2636	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	3	9,7	28	90,3	33	32,7	5	15,2	28	84,8	0,5096	0,62	0,15	2,60	Convergence criterion (GCONV=1E-8) satisfied.	0,0024
	IIB	27	26,0	2	7,4	25	92,6	15	14,9	0	0,0	15	100,0	0,2024	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	9	19,6	37	80,4	53	52,5	0	0,0	53	100,0	0,0007	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MHP_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:17

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					Interaction Test
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	p-value (likelihood ratio)
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	5	4,8	99	95,2	101	100,0	0	0	101	100,0	0,0255	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	0	0	71	100,0	0,0616	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2553	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0	62	100,0	0,0836	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1595	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	0	0	23	100,0	0,2002	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	0	0	68	100,0	0,0767	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	5	10,9	41	89,1	53	52,5	0	0	53	100,0	0,0139	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MHP35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:19

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3066	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3501	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3103	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,2884	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2532	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MHP5_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care (BSC) (N=101)						Atezolizumab vs. Best Supportive Care (BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	6	5,8	98	94,2	101	100,0	0	0	101	100,0	0,0149	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	5	6,1	77	93,9	71	70,3	0	0	71	100,0	0,0361	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2410	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	3	4,7	61	95,3	62	61,4	0	0	62	100,0	0,0808	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9978
	>= 65	40	38,5	3	7,5	37	92,5	39	38,6	0	0	39	100,0	0,0846	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	4	13,8	25	86,2	23	22,8	0	0	23	100,0	0,0664	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1505	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	3	9,7	28	90,3	33	32,7	0	0	33	100,0	0,0700	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0	53	100,0	0,0622	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMPN_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3560	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3297	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMPN35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pneumonitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1635	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0	71	100,0	0,1886	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1627	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3062	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,3022	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2924	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMPNS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:45

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Interaction Test	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	5	4,8	99	95,2	101	100,0	2	2,0	99	98,0	0,2556	2,51	0,49	12,94	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	4	4,9	78	95,1	71	70,3	1	1,4	70	98,6	0,2338	3,49	0,39	31,28	Convergence criterion (GCONV=1E-8) satisfied.	0,6208
	Female	22	21,2	1	4,5	21	95,5	30	29,7	1	3,3	29	96,7	0,7851	1,47	0,09	23,50	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	5	7,8	59	92,2	62	61,4	1	1,6	61	98,4	0,0975	5,11	0,60	43,80	Convergence criterion (GCONV=1E-8) satisfied.	0,0798
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	1	2,6	38	97,4	0,3238	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	2	6,9	27	93,1	23	22,8	1	4,3	22	95,7	0,6916	1,62	0,14	18,18	Convergence criterion (GCONV=1E-8) satisfied.	0,9265
	Europe and Middle East	65	62,5	3	4,6	62	95,4	68	67,3	1	1,5	67	98,5	0,2893	3,18	0,33	30,62	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0,0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	2	6,5	29	93,5	33	32,7	2	6,1	31	93,9	0,9069	1,12	0,16	7,99	Convergence criterion (GCONV=1E-8) satisfied.	0,2232
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0,0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	3	6,5	43	93,5	53	52,5	0	0,0	53	100,0	0,0589	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMHT_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MHT35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMHTS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1571	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	2	2,4	80	97,6	71	70,3	0	0	71	100,0	0,1831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9971
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	>= 65	40	38,5	2	5,0	38	95,0	39	38,6	0	0	39	100,0	0,1542	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3732	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,2943	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1236	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMSR_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMSR35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMSRS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:20

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3794	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:47

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3325	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3411	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3794	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	1	3,2	30	96,8	33	32,7	0	0	33	100,0	0,2994	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMCL35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Colitis Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:52

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIME_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 9:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIME35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 9:59

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	2	1,9	102	98,1	101	100,0	0	0	101	100,0	0,1624	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9958
	Female	22	21,2	2	9,1	20	90,9	30	29,7	0	0	30	100,0	0,0948	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9979
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	2	3,1	63	96,9	68	67,3	0	0	68	100,0	0,1465	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	2	4,3	44	95,7	53	52,5	0	0	53	100,0	0,1269	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMES_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:02

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMI_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMI35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Meningitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3234	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMIS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMEP_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:48

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Encephalitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMEPS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMGB_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMG35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:56

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3244	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0,0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9970
	Female	22	21,2	1	4,5	21	95,5	30	29,7	0	0	30	100,0	0,2429	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	1	1,6	63	98,4	62	61,4	0	0	62	100,0	0,3250	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	0	0,0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0,0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	1	1,5	64	98,5	68	67,3	0	0	68	100,0	0,3064	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	0	0,0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	1	2,2	45	97,8	53	52,5	0	0	53	100,0	0,2831	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMGBS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III/A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	104	100,0	1	1,0	103	99,0	101	100,0	0	0	101	100,0	0,3117	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	1	1,2	81	98,8	71	70,3	0	0	71	100,0	0,3516	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9966
	Female	22	21,2	0	0,0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0,0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,9965
	>= 65	40	38,5	1	2,5	39	97,5	39	38,6	0	0	39	100,0	0,3324	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	1	3,4	28	96,6	23	22,8	0	0	23	100,0	0,3634	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	Europe and Middle East	65	62,5	0	0,0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0,0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0,0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	1,0000
	IIB	27	26,0	1	3,7	26	96,2	15	14,9	0	0	15	100,0	0,4795	>999,99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0,0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:51

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Grade >= 3
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMOT35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:55

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Autoimmune Hemolytic Anemia
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTAHA_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Autoimmune Hemolytic Anemia Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTAHA35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Autoimmune Hemolytic Anemia Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTHAS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MA1_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:36

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1M135_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:38

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMAIS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 12:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III/A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Diabetes mellitus
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMDM_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:15

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Diabetes mellitus Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMDM35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:16

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Diabetes mellitus Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMDMS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:18

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypophysitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MLH_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:04

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypophysitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MLH35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Hypophysitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TT1MLHS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myocarditis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMC_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:10

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myocarditis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMM35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:12

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myocarditis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMCS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMMG_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 13:00

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMG35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 13:02

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTMMGS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 13:05

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myositis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMMY_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:20

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myositis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMMY35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Myositis Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMYS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Nephritis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMNP_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Nephritis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTINP35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Nephritis Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMNPS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pancreatitis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMPC_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pancreatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMPC35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Vasculitis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMVS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Vasculitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMVS35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Vasculitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIMVSS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 11:02

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Infusion-Related Reactions
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.s1s
 27JUN2022 10:04

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Infusion-Related Reactions Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIRR35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:06

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Infusion-Related Reactions Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTIRRS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Rhabdomyolysis
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/G029527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Rhabdomyolysis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_tte_sg_TTRHAB35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
 27JUN2022 10:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Rhabdomyolysis Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
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 27JUN2022 10:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Time to First Immune-Mediated Pancreatitis Serious
 MODEL: Unstratified analysis
 STUDY: G029527
 Time to Event Analysis by Subgroups (Safety)

		Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio			Convergence Status	Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		
All	n/a	104	100,0	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	82	78,8	0	0	82	100,0	71	70,3	0	0	71	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Female	22	21,2	0	0	22	100,0	30	29,7	0	0	30	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	64	61,5	0	0	64	100,0	62	61,4	0	0	62	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	>= 65	40	38,5	0	0	40	100,0	39	38,6	0	0	39	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	29	27,9	0	0	29	100,0	23	22,8	0	0	23	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	Europe and Middle East	65	62,5	0	0	65	100,0	68	67,3	0	0	68	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,6	0	0	10	100,0	10	9,9	0	0	10	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Tumor stage per eCRF	IIA	31	29,8	0	0	31	100,0	33	32,7	0	0	33	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	NE
	IIB	27	26,0	0	0	27	100,0	15	14,9	0	0	15	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	46	44,2	0	0	46	100,0	53	52,5	0	0	53	100,0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
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 27JUN2022 10:13

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

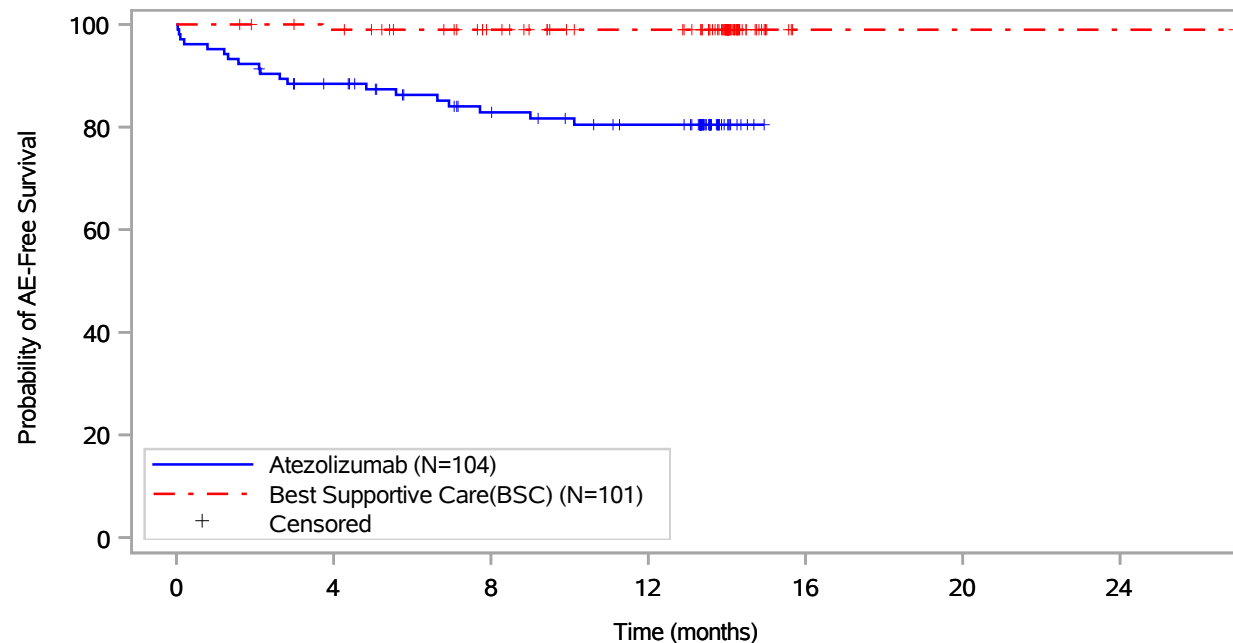
Spezifische Verträglichkeit

KM Plots

Unstratifiziert

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash
STUDY: GO29527



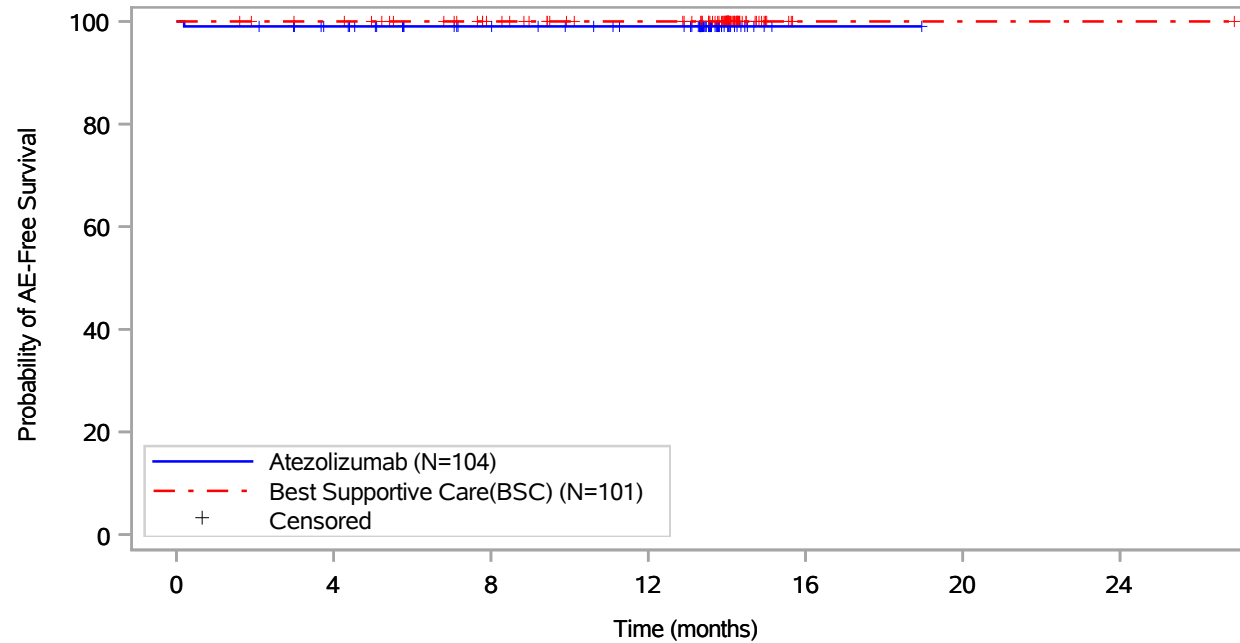
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	86	71	63	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	85	76	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	6	16	22	NE	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 12:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash Grade \geq 3
STUDY: GO29527



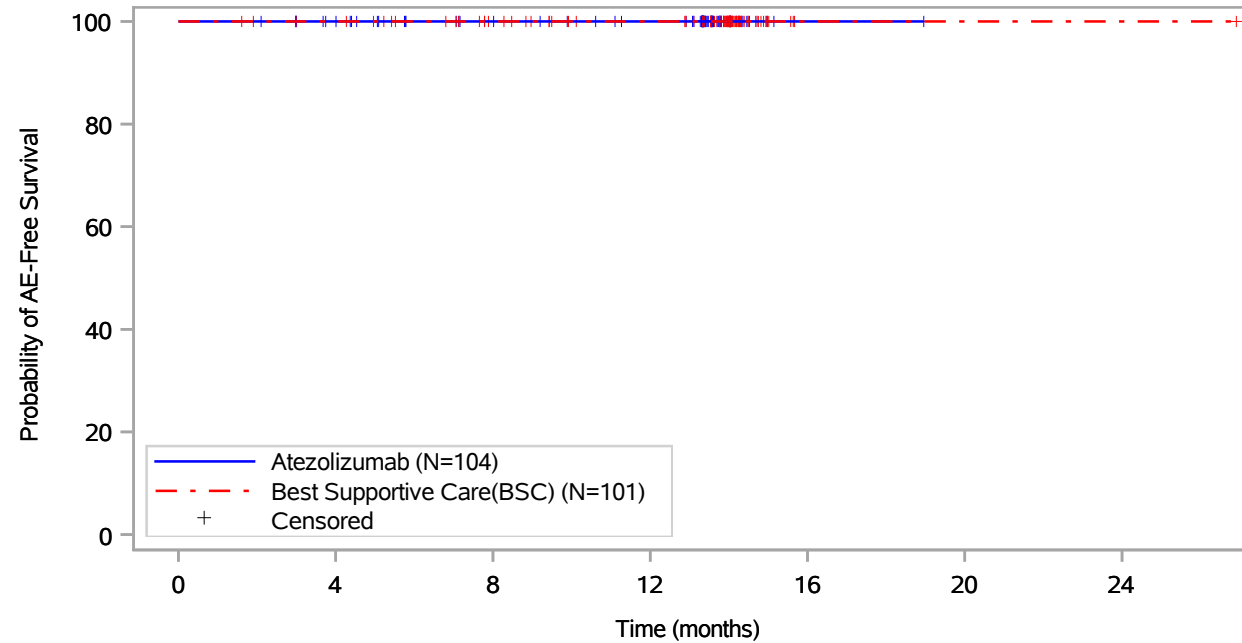
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 13:01

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Rash Serious
STUDY: GO29527



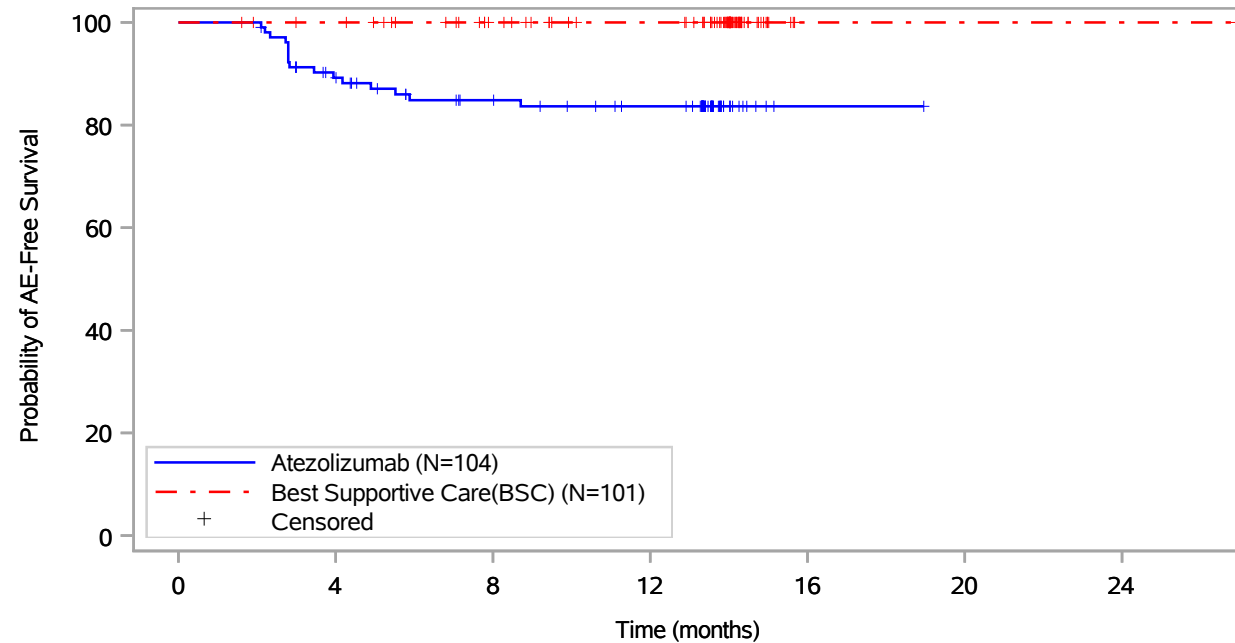
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 13:03

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluatable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism
STUDY: GO29527



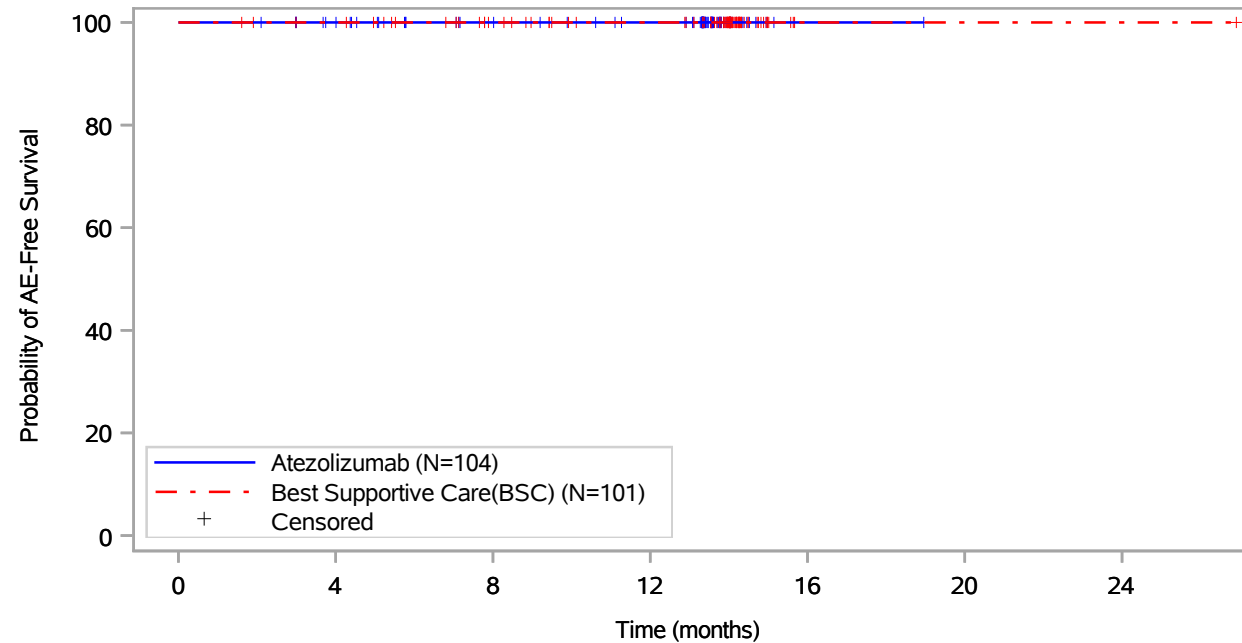
Patients at risk							
Atezolizumab (N=104)	104	86	72	65	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	17	23	87	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 15:00

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism Grade \geq 3
STUDY: GO29527



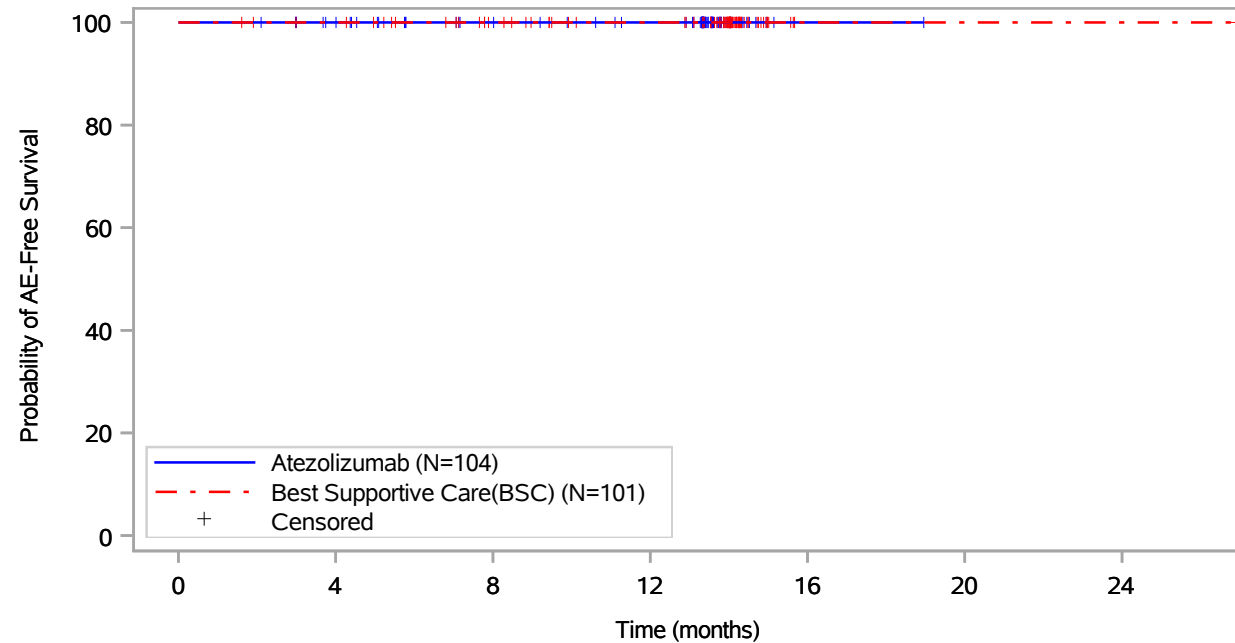
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 15:01

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypothyroidism Serious
STUDY: GO29527



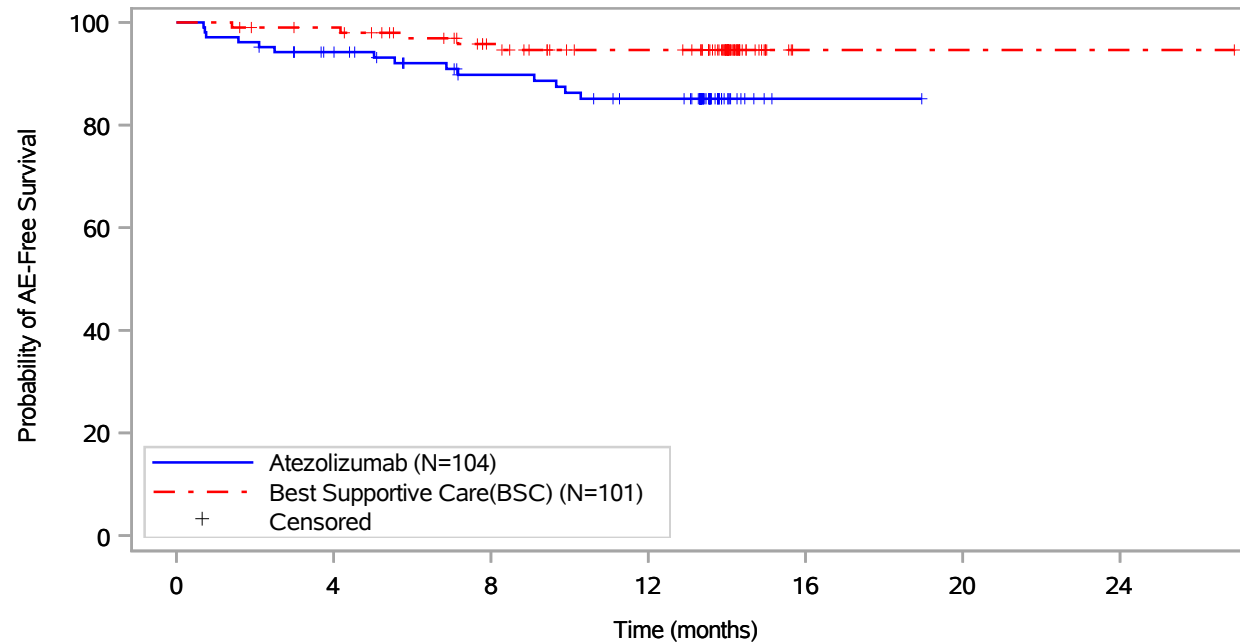
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 15:03

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis
STUDY: GO29527



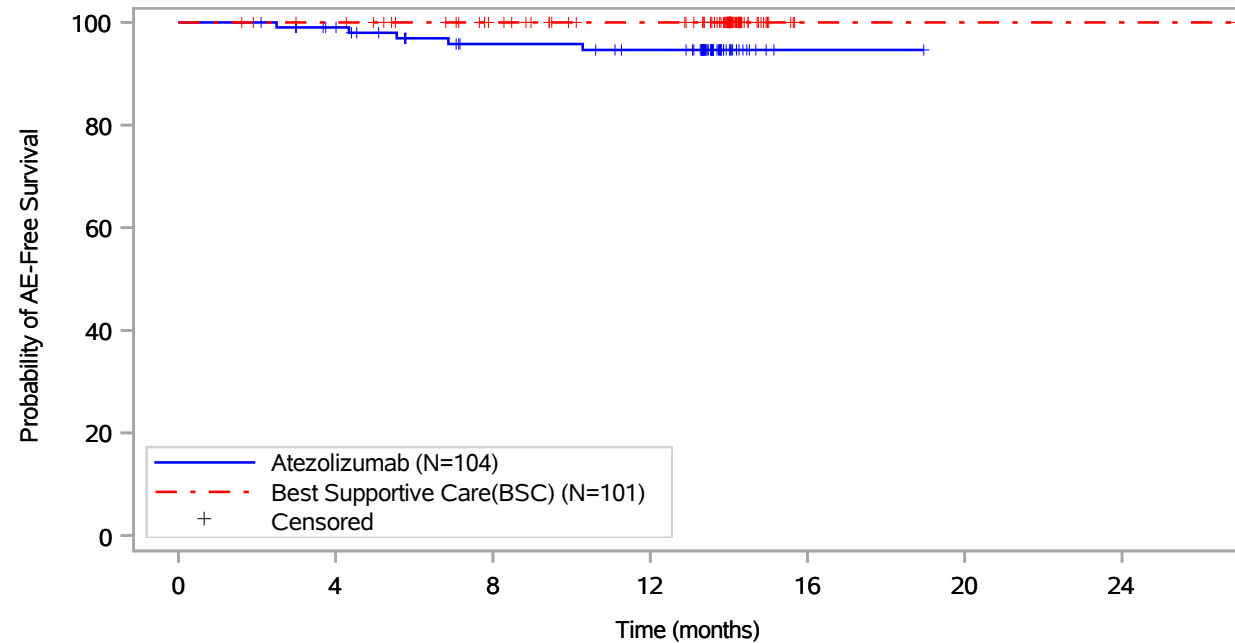
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	91	77	70	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	97	82	72	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	17	20	89	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

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 27JUN2022 14:54

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis Grade \geq 3
STUDY: GO29527



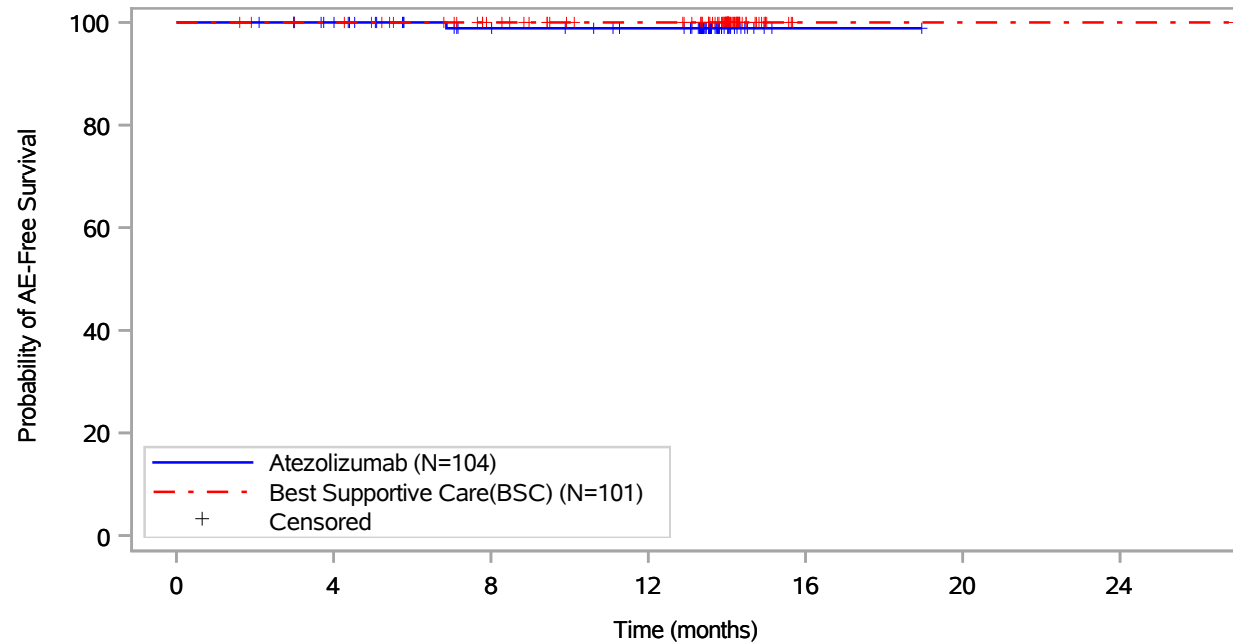
Patients at risk							
Atezolizumab (N=104)	104	96	83	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	17	20	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 14:56

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hepatitis Serious
STUDY: GO29527



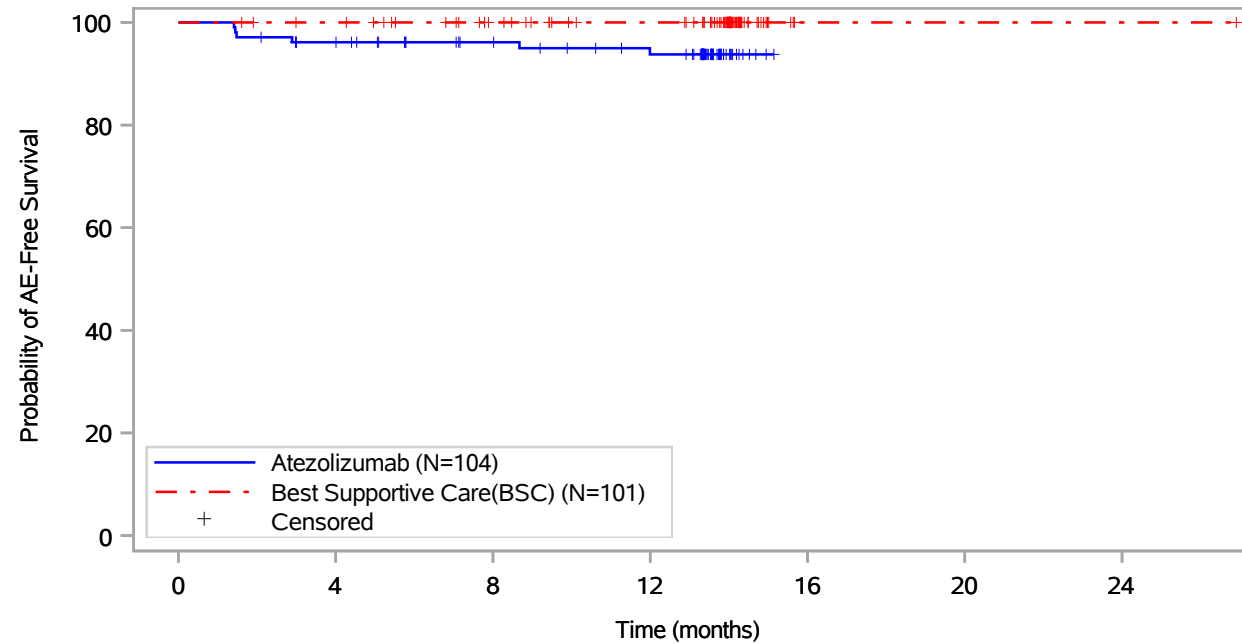
Patients at risk							
Atezolizumab (N=104)	104	97	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 14:58

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis
STUDY: GO29527



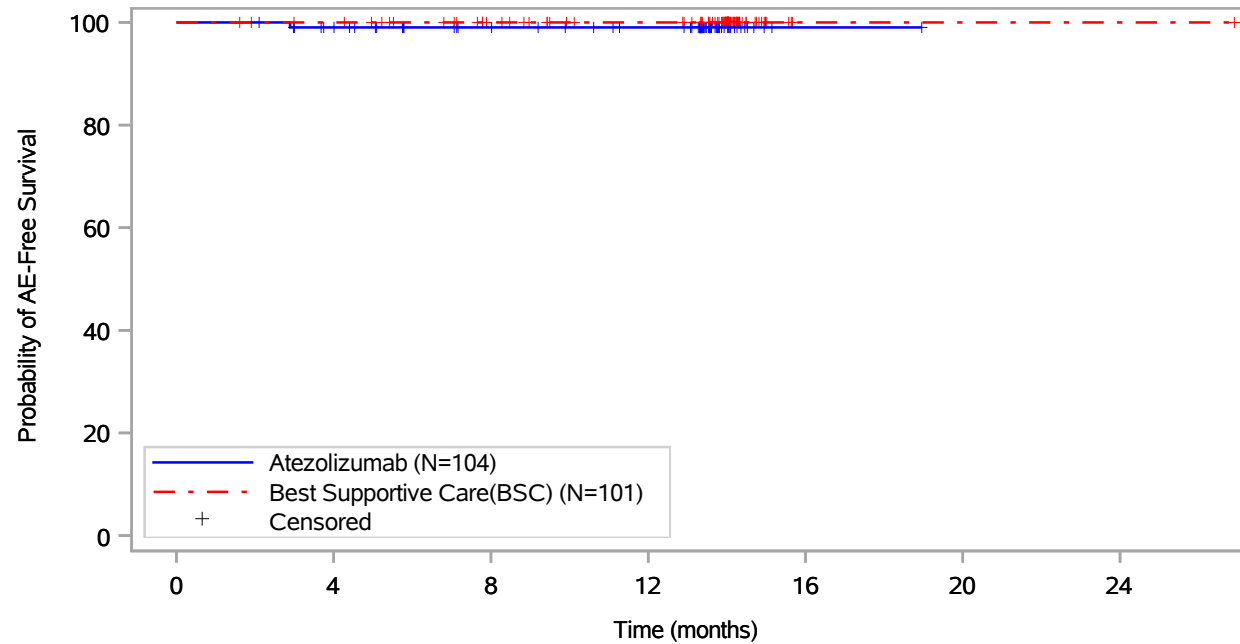
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	95	84	77	NE	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	5	16	21	NE	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 15:16

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis Grade \geq 3
STUDY: GO29527



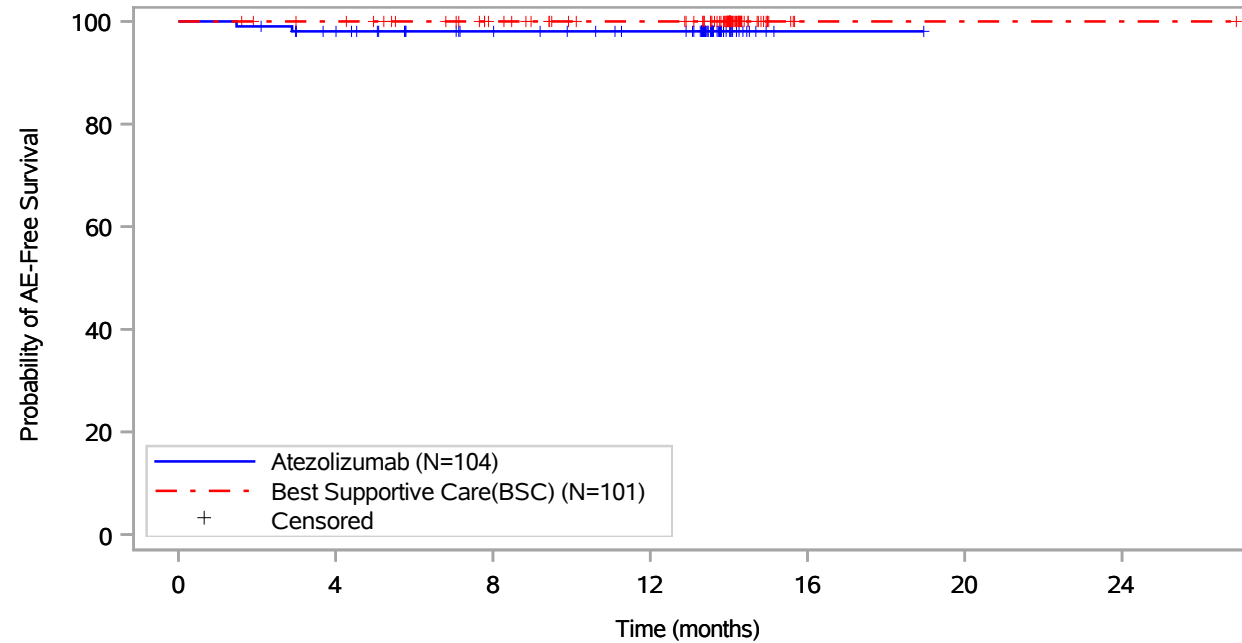
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
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 27JUN2022 15:18

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pneumonitis Serious
STUDY: GO29527



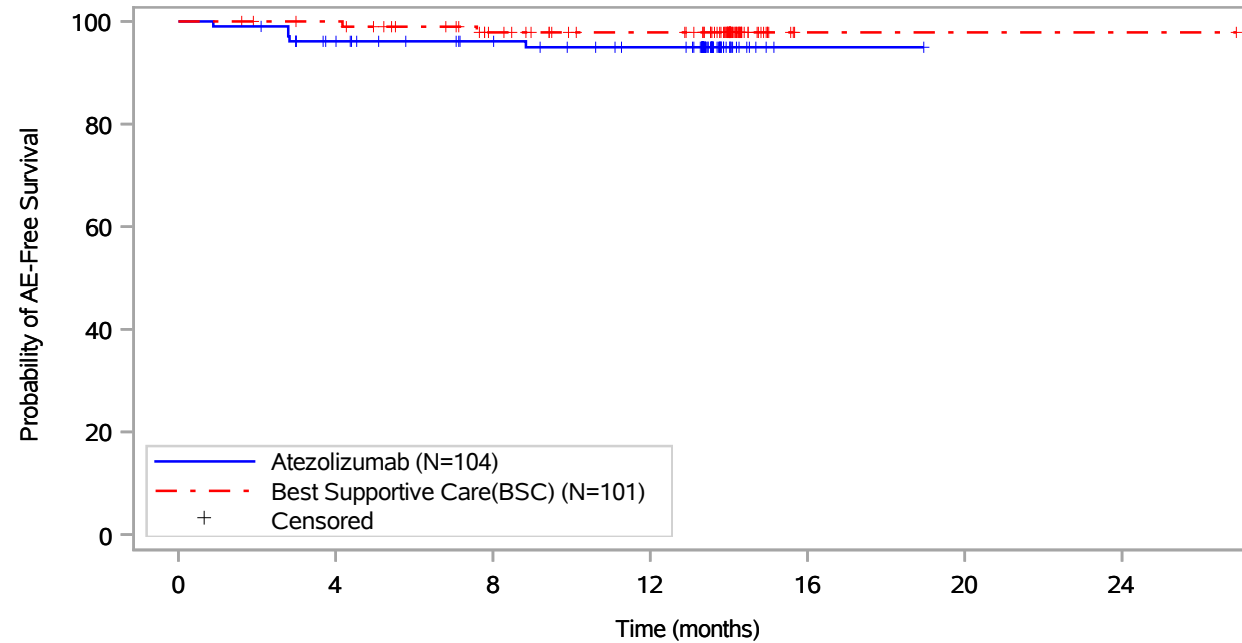
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIPNS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:19

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism
STUDY: GO29527



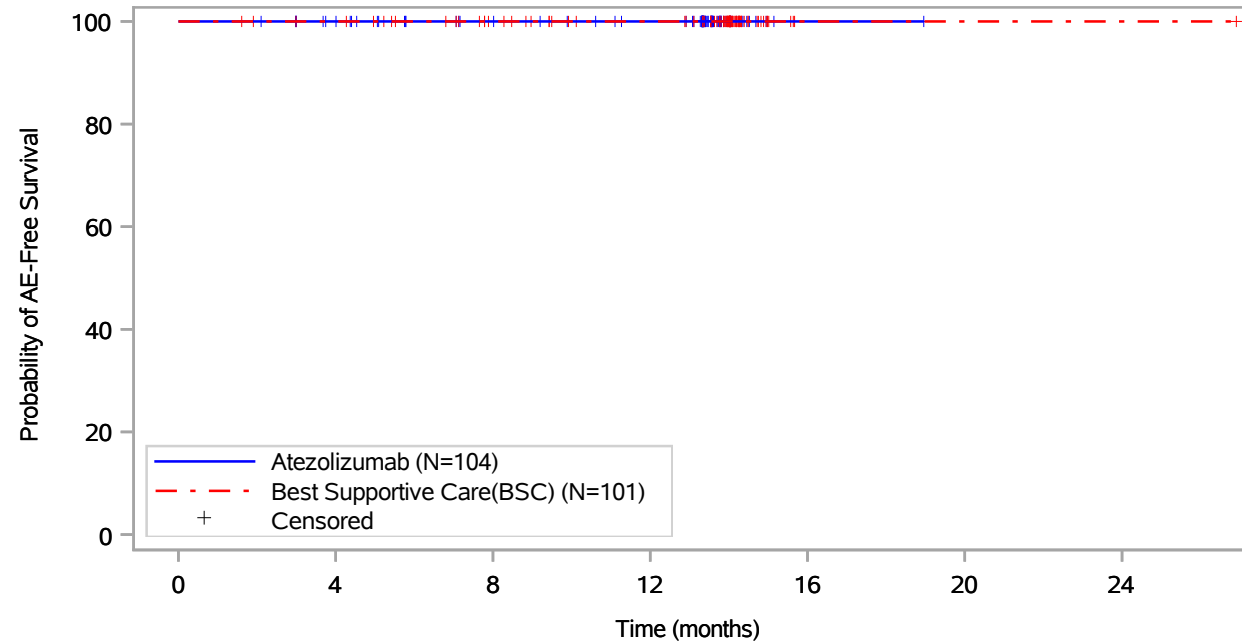
Patients at risk							
Atezolizumab (N=104)	104	93	84	77	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	84	75	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	16	22	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMHT_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:05

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Grade \geq 3
STUDY: GO29527



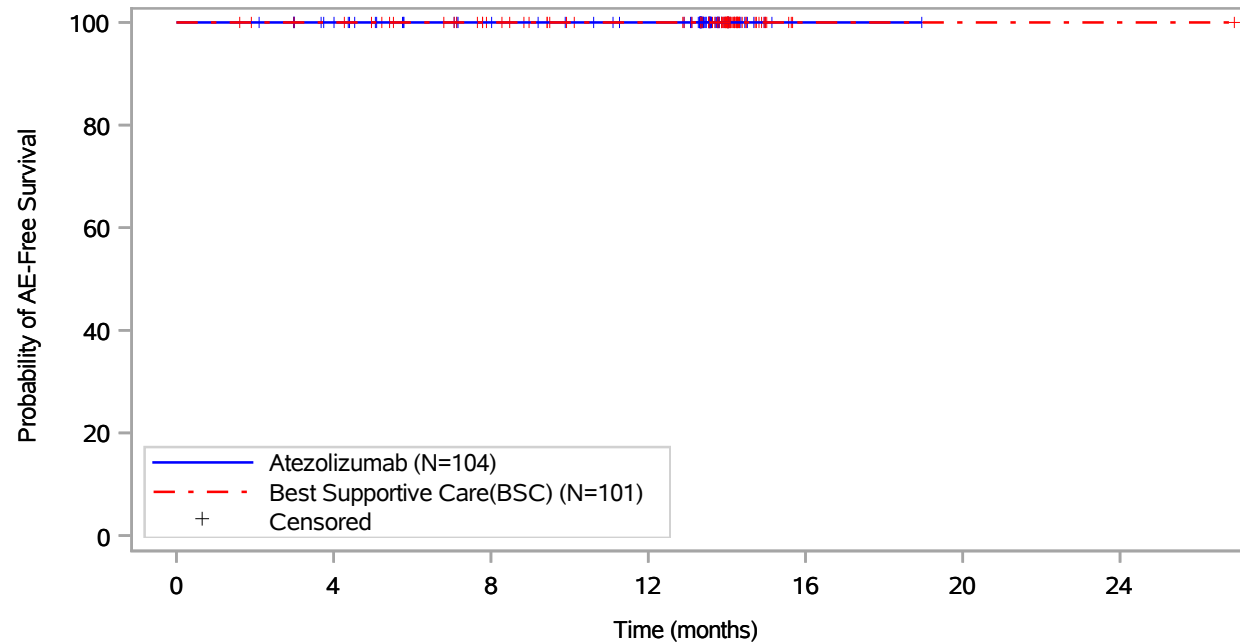
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMHT35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hyperthyroidism Serious
STUDY: GO29527



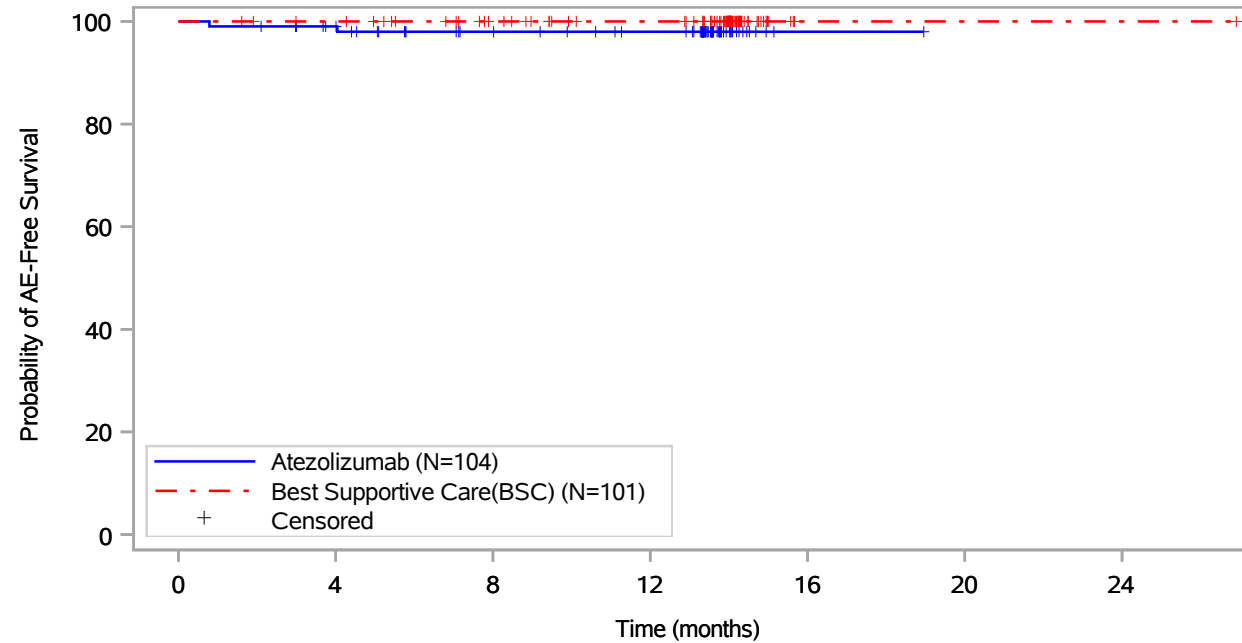
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMHTS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:09

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions
STUDY: GO29527



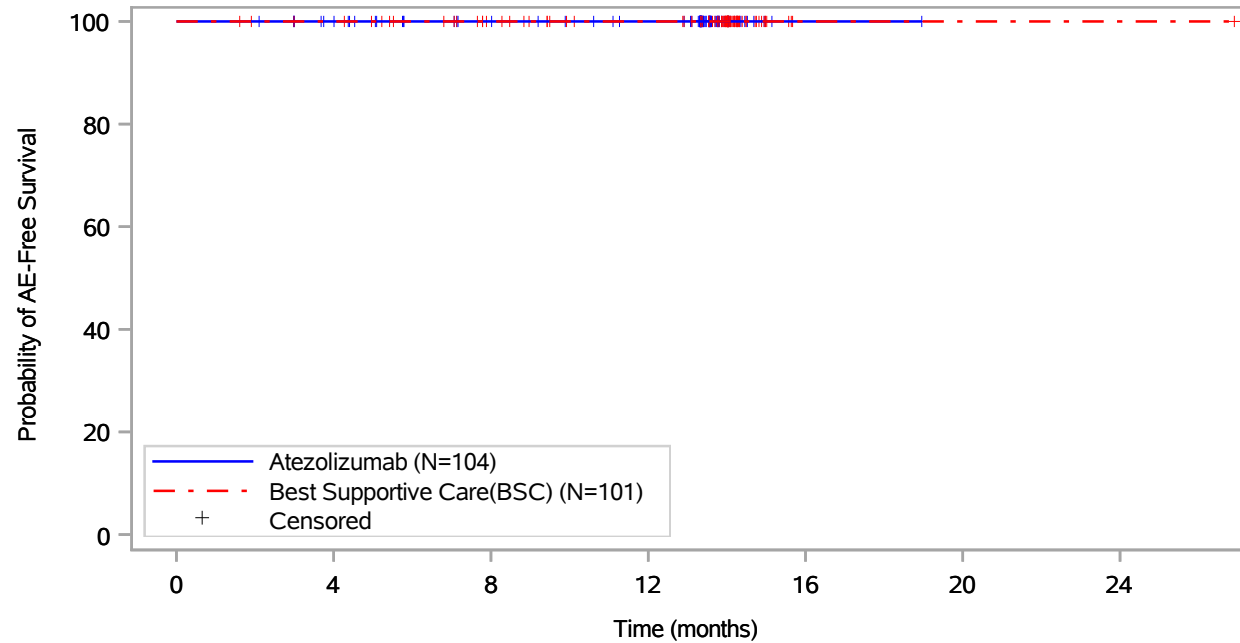
Patients at risk							
Atezolizumab (N=104)	104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: .../ACE_OS_IA/prod/output/g_km_TTIMSR_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:36

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Grade >= 3
STUDY: GO29527



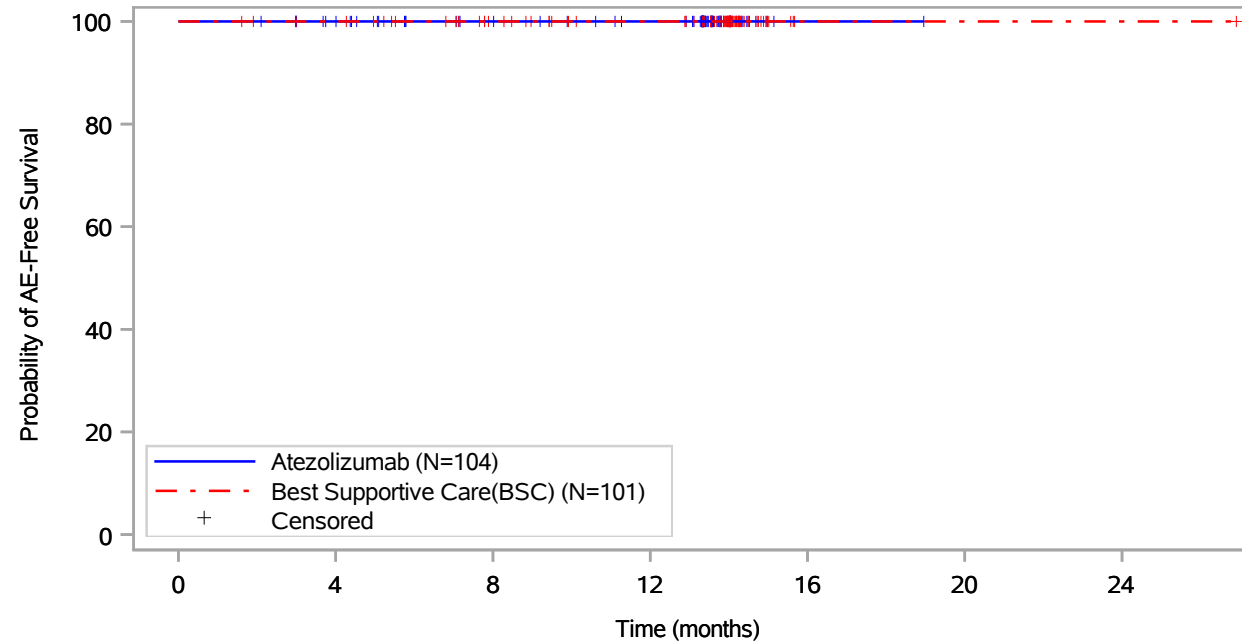
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMSR35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:38

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Severe Cutaneous Reactions Serious
STUDY: GO29527



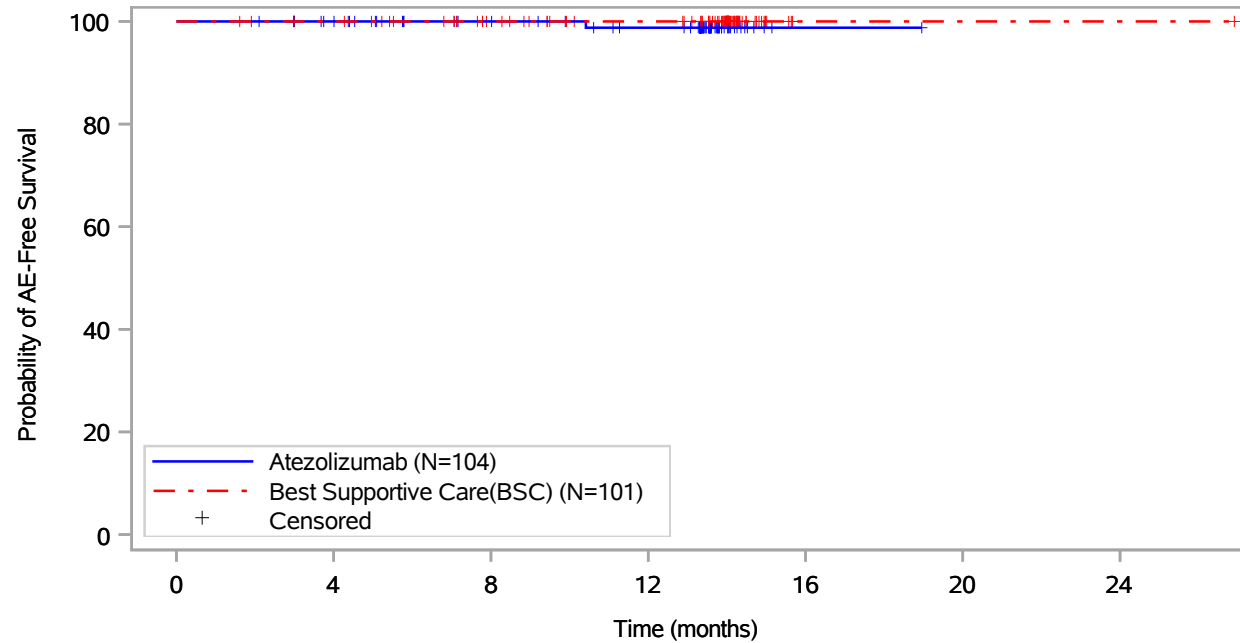
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMSRS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis
STUDY: GO29527



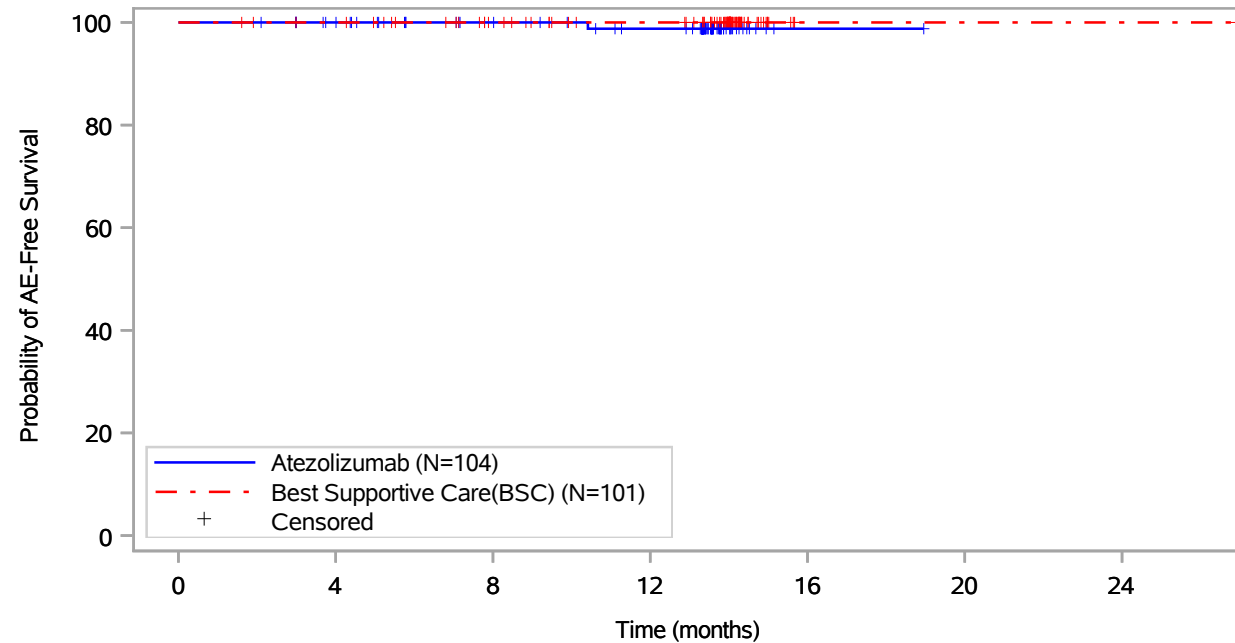
Patients at risk							
Atezolizumab (N=104)	104	97	85	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis Grade >= 3
STUDY: GO29527



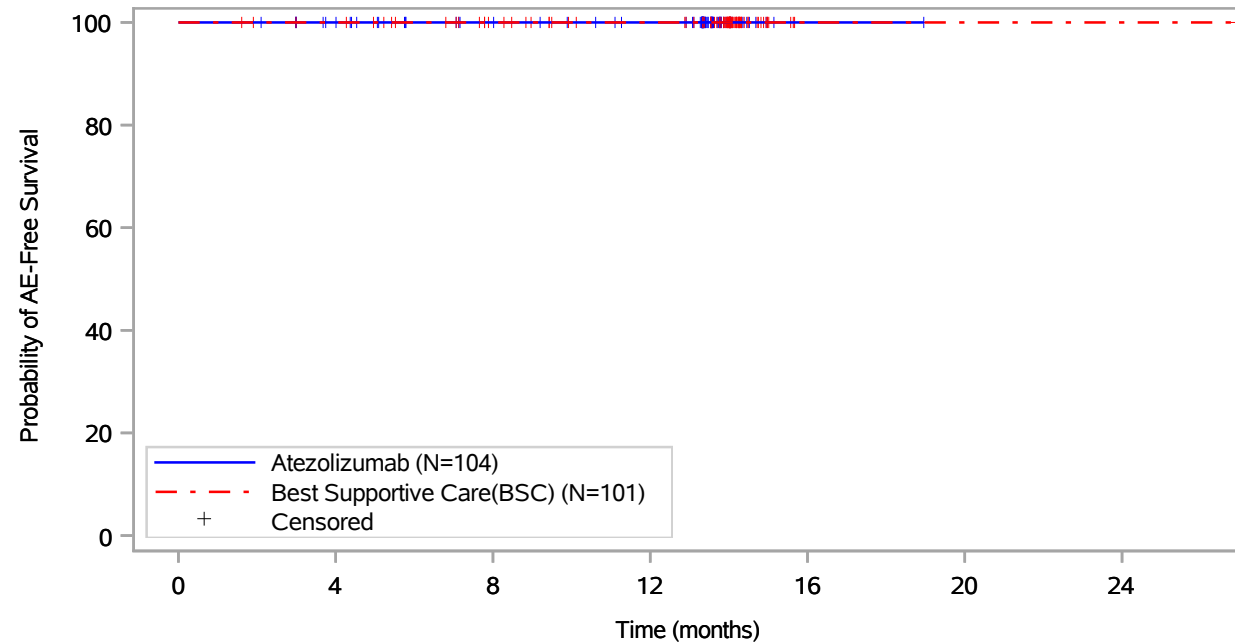
Patients at risk							
Atezolizumab (N=104)	104	97	85	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMCL35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Colitis Serious
STUDY: GO29527



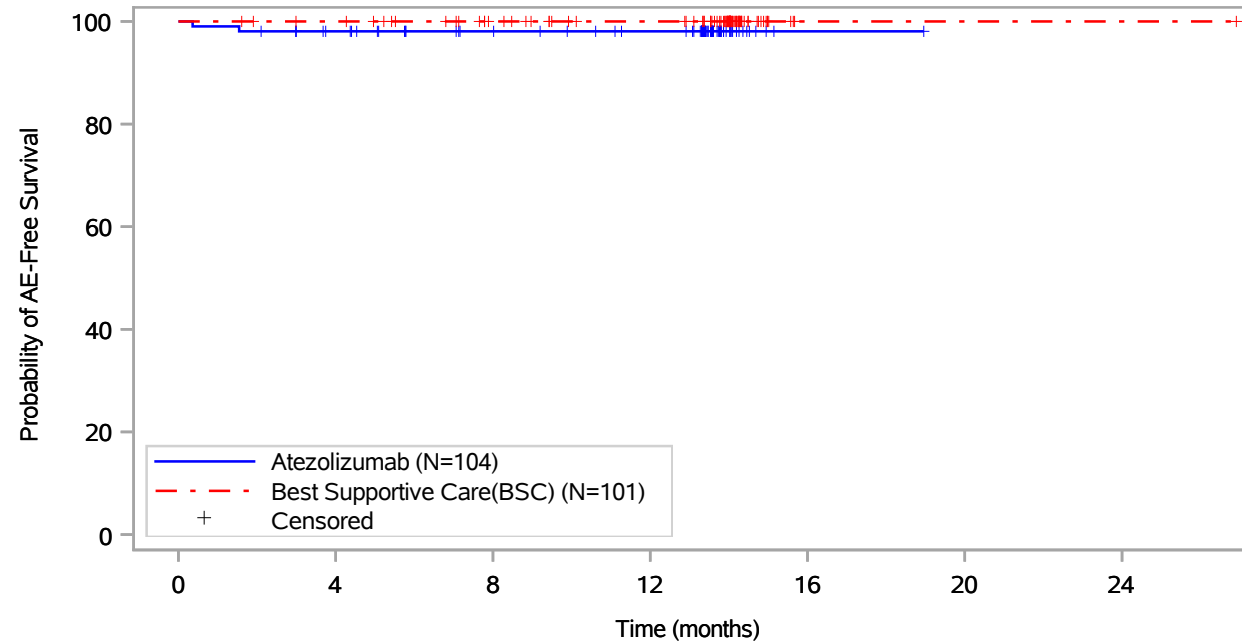
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:24

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis
STUDY: GO29527



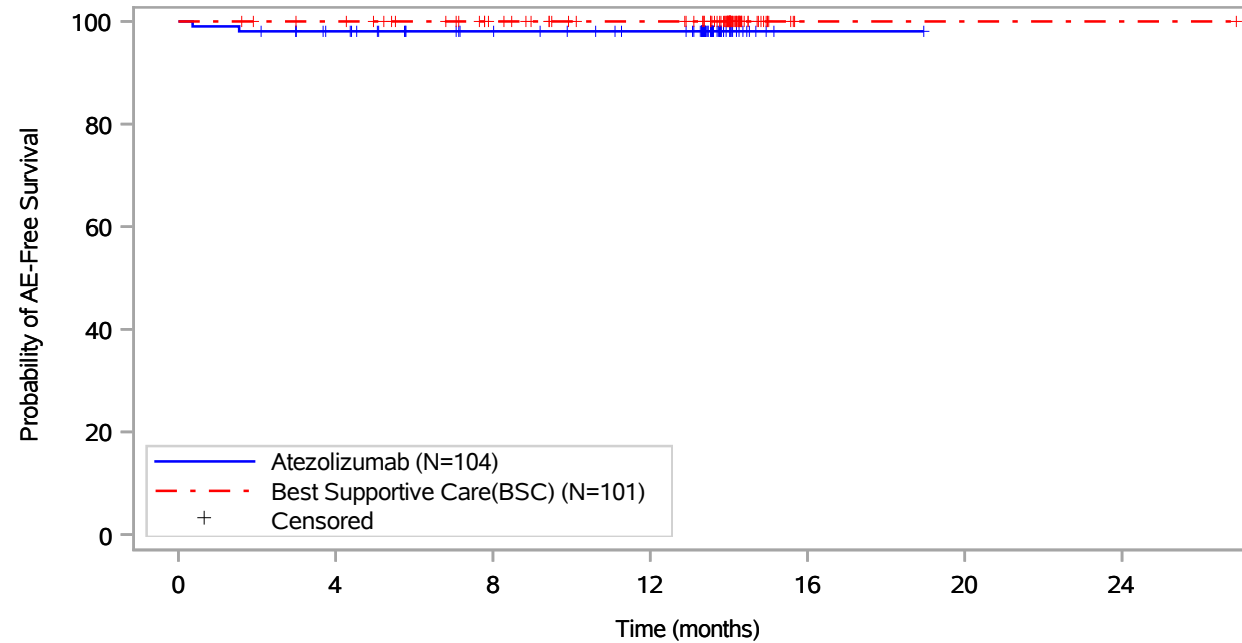
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: .../ACE_OS_IA/prod/output/g_km_TTIMME_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Grade >= 3
STUDY: GO29527



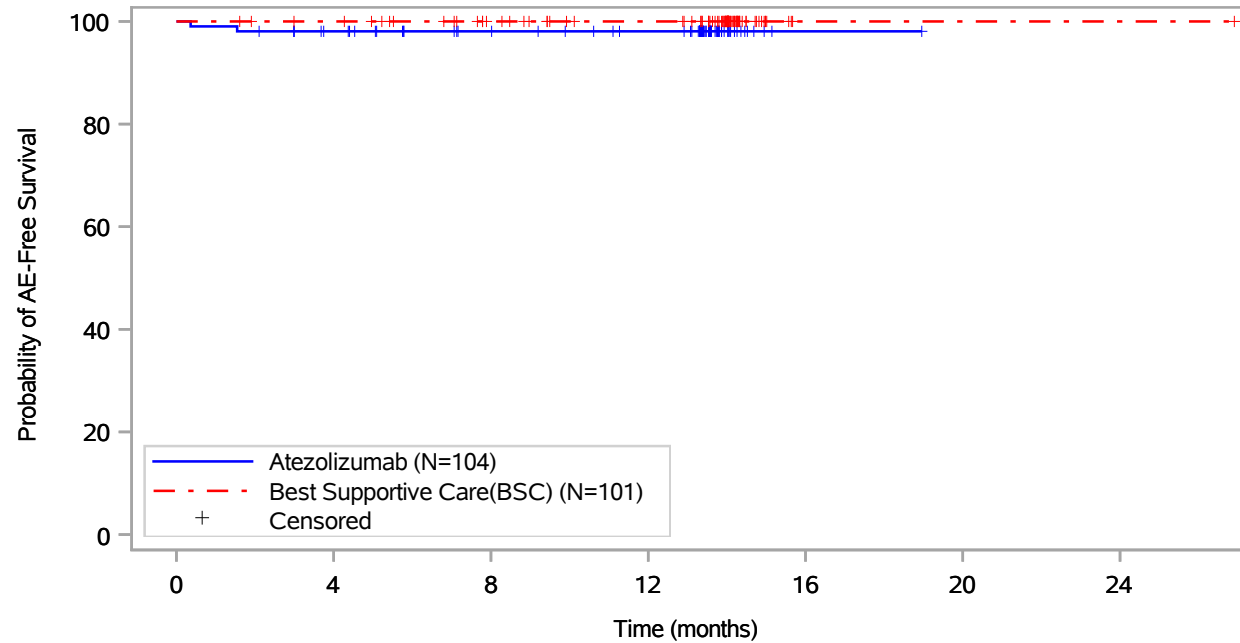
Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMME35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:22

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningoencephalitis Serious
STUDY: GO29527



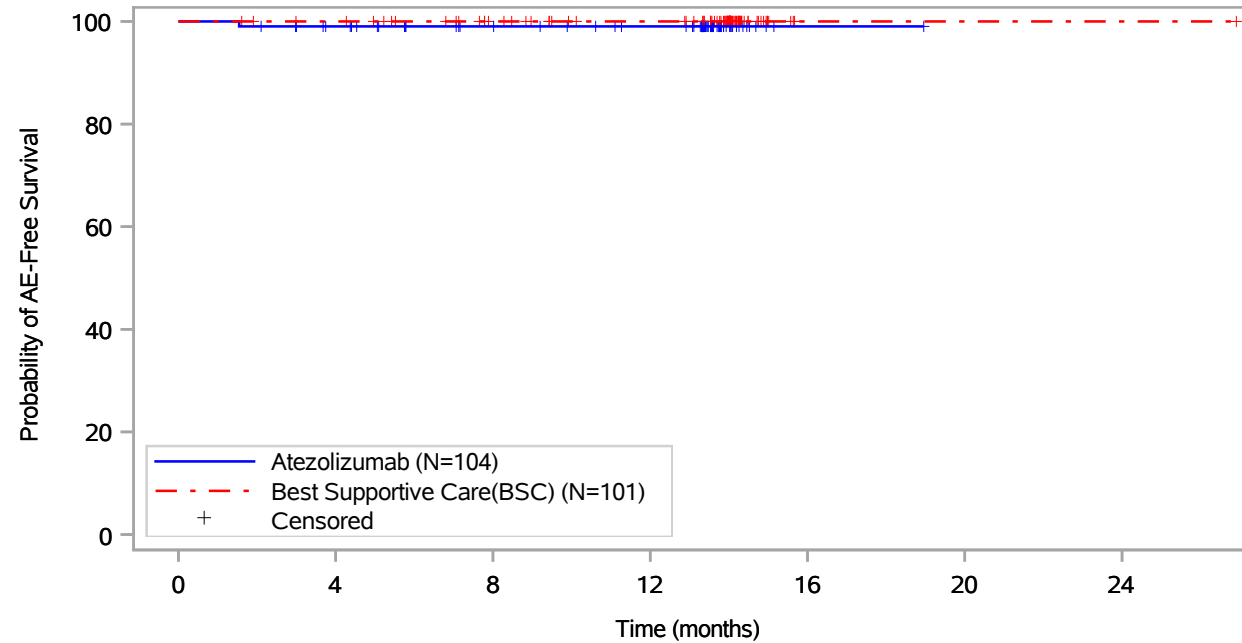
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMES_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:24

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis
STUDY: GO29527



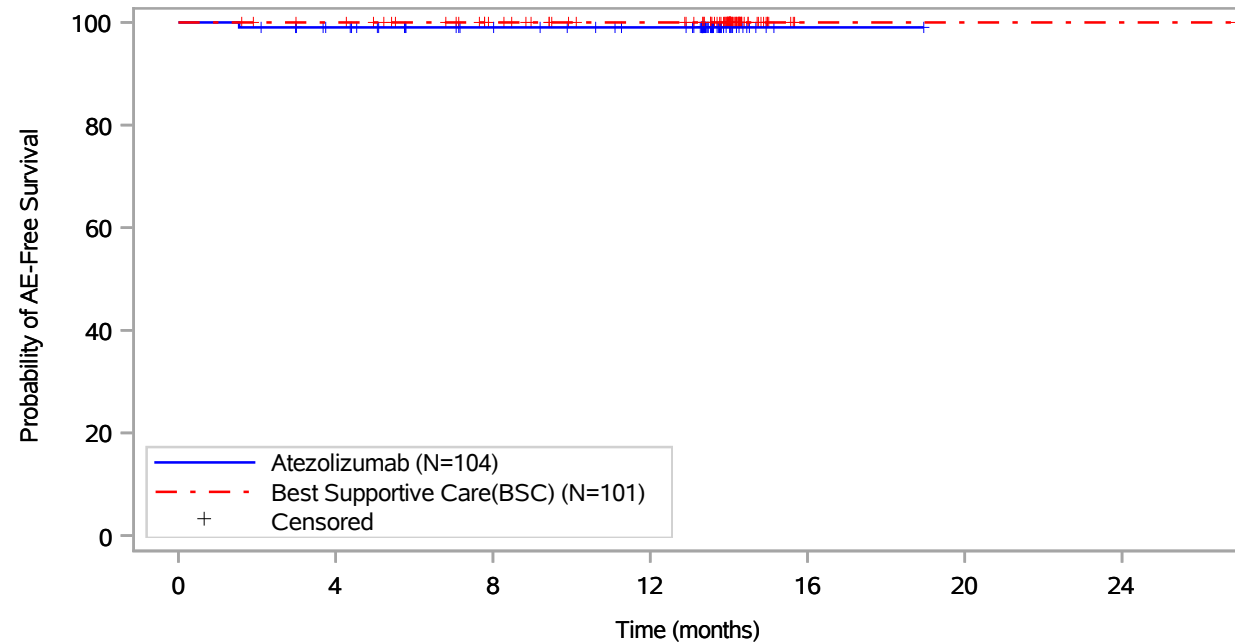
Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_OS_IA/prod/output/g_km_TTIMMI_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:05

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis Grade \geq 3
STUDY: GO29527



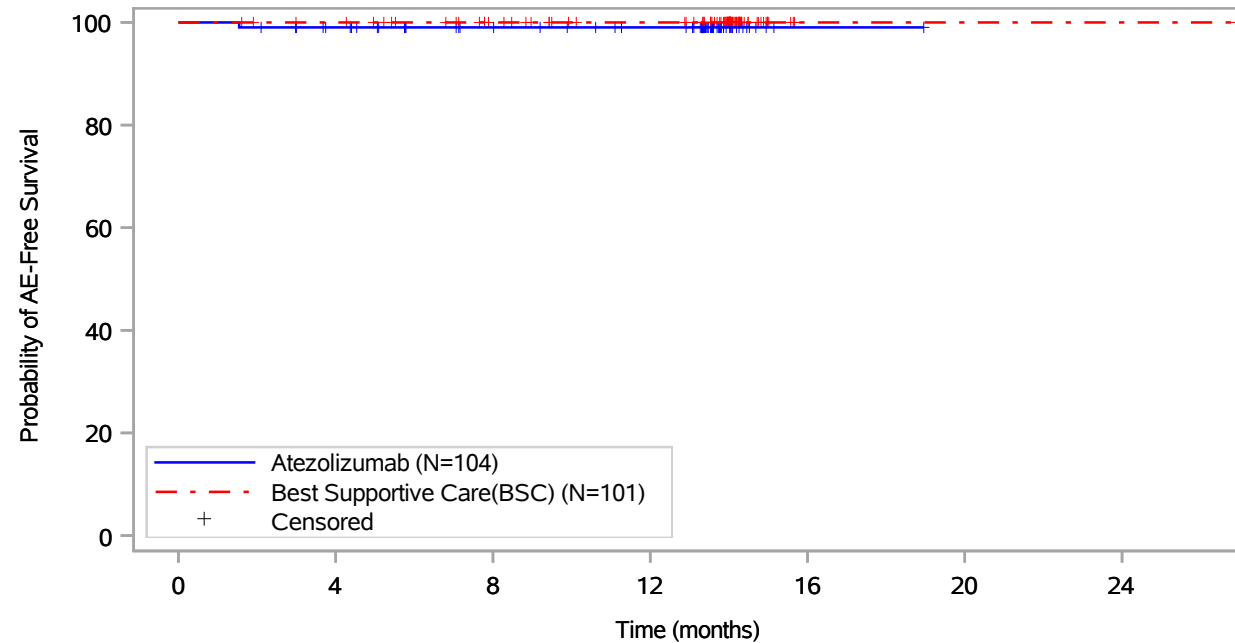
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMMI35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:07

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Meningitis Serious
STUDY: GO29527



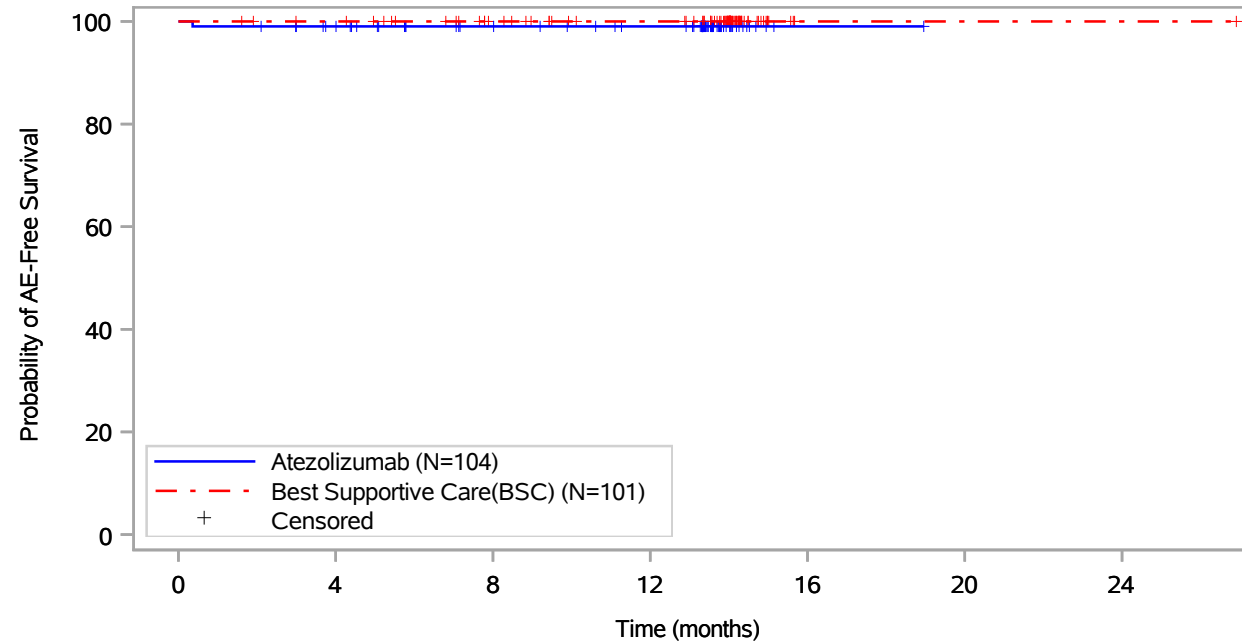
Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMIS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:08

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis
STUDY: GO29527



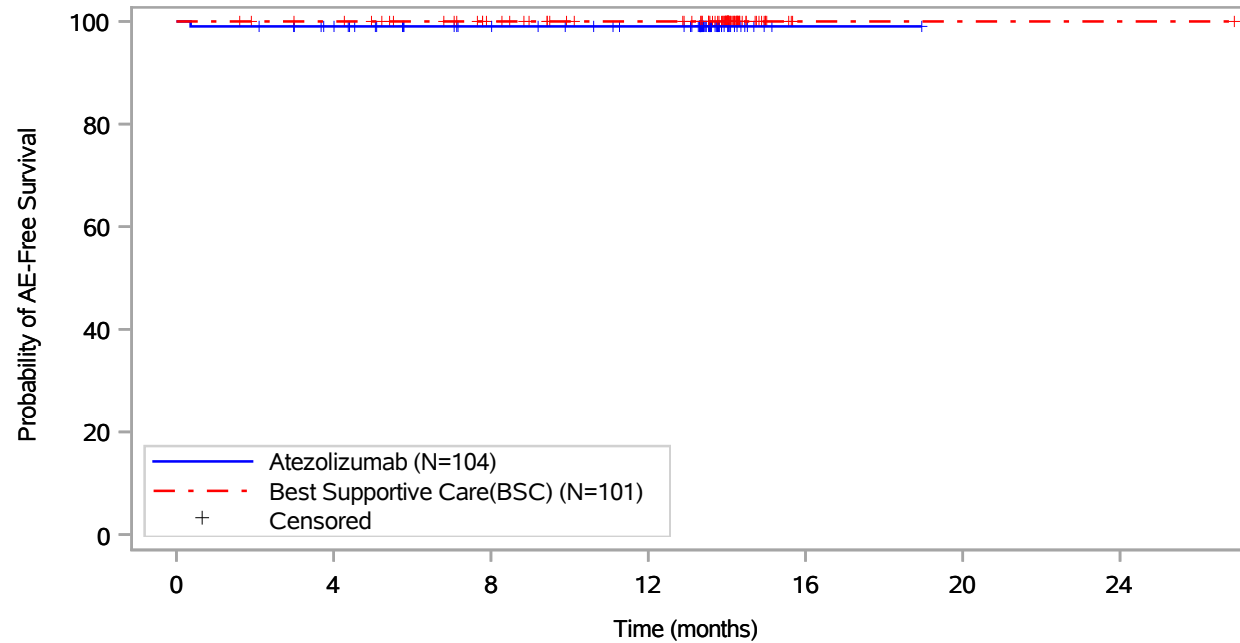
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMEP_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:10

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis Grade >= 3
STUDY: GO29527



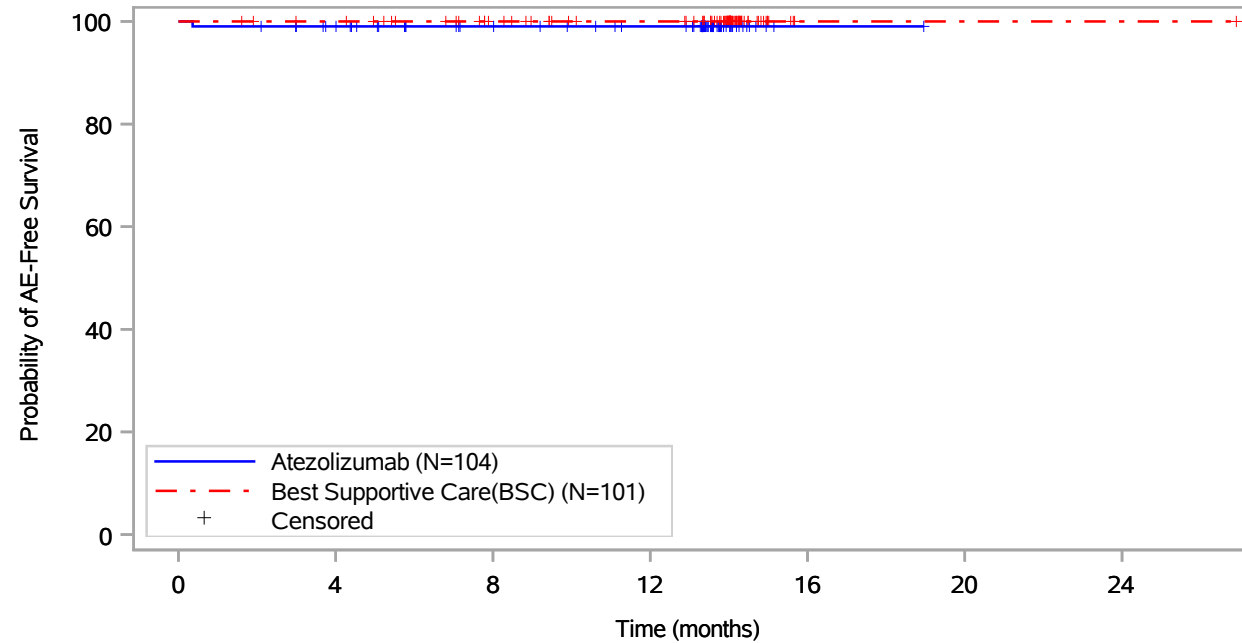
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Encephalitis Serious
STUDY: GO29527



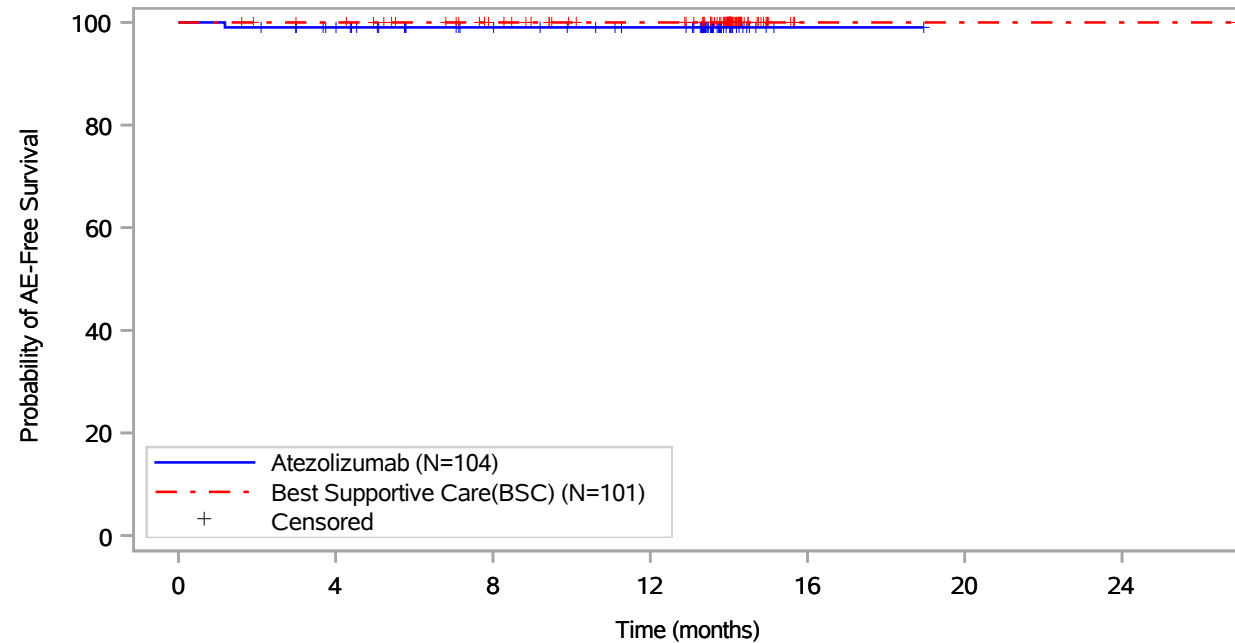
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMEPS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:13

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome
STUDY: GO29527



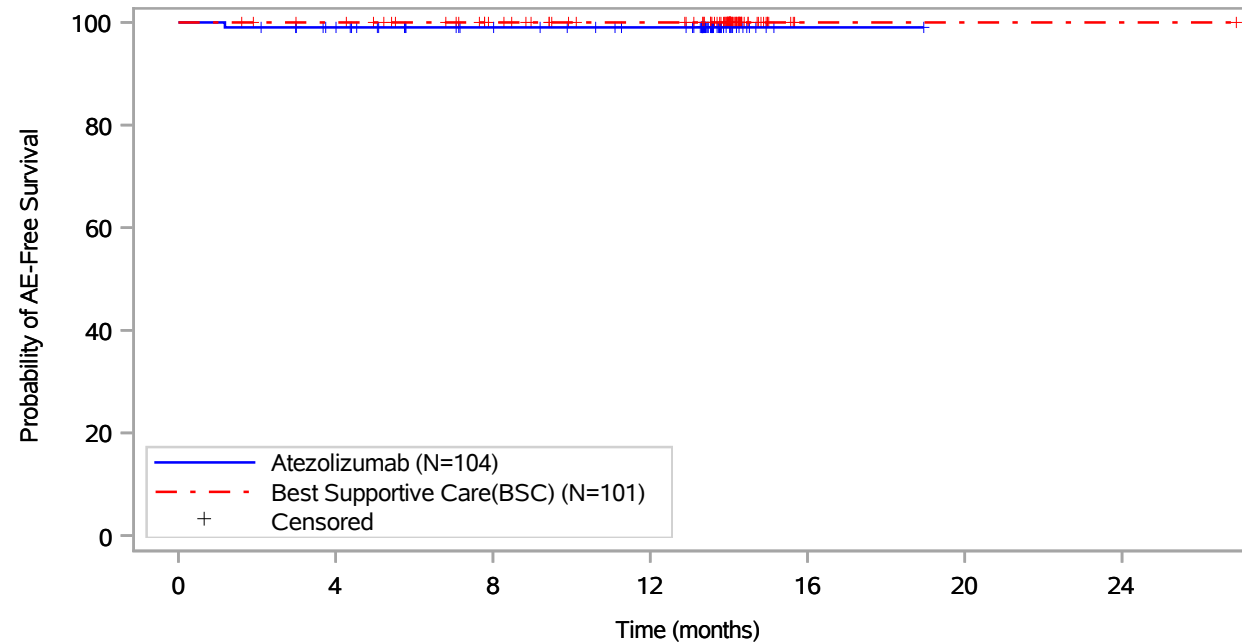
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...s/ACE_OS_IA/prod/output/g_km_TTIMGB_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:26

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Grade >= 3
STUDY: GO29527



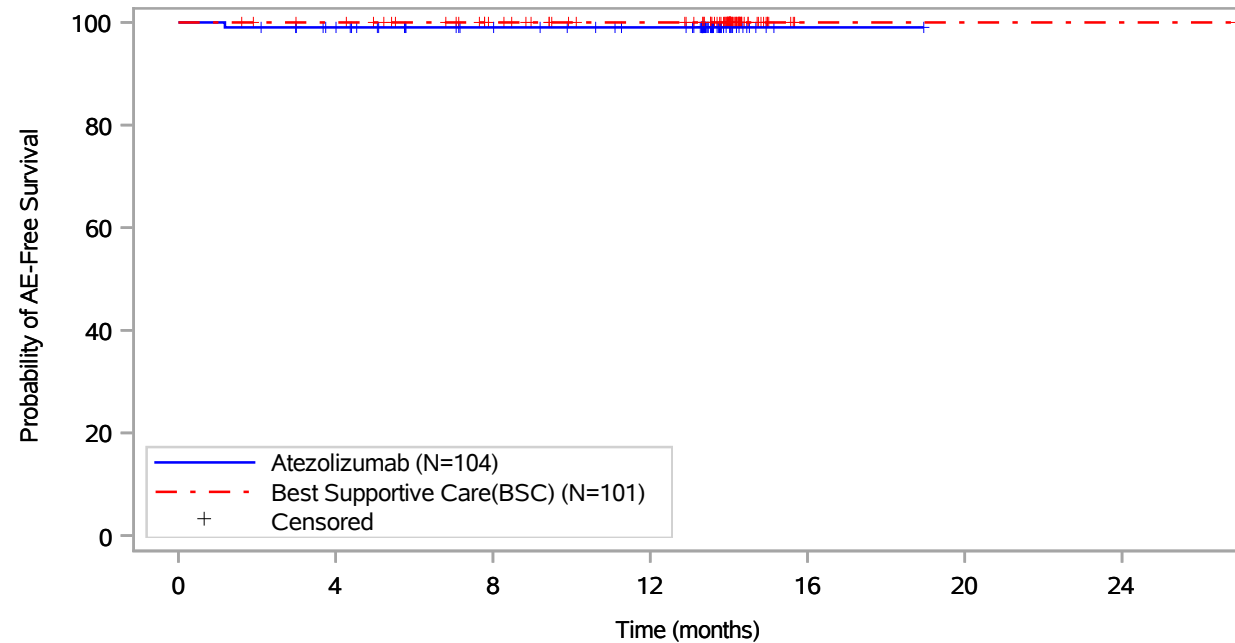
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMGB35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Guillain-Barre Syndrome Serious
STUDY: GO29527



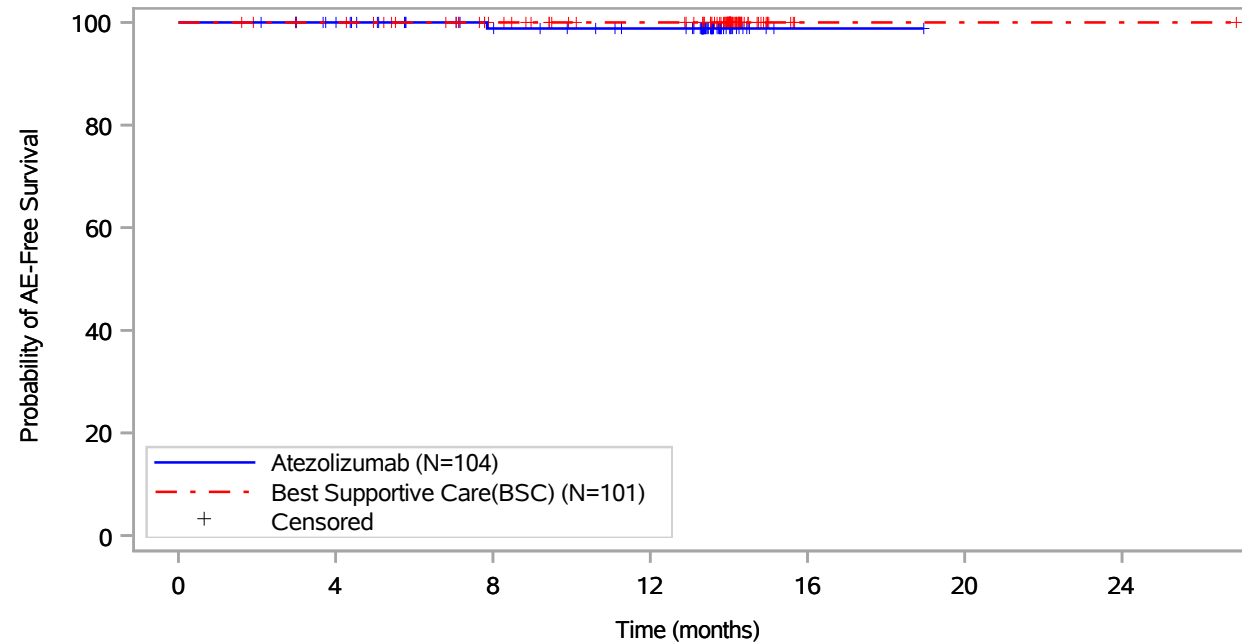
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMGBS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:29

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity
STUDY: GO29527



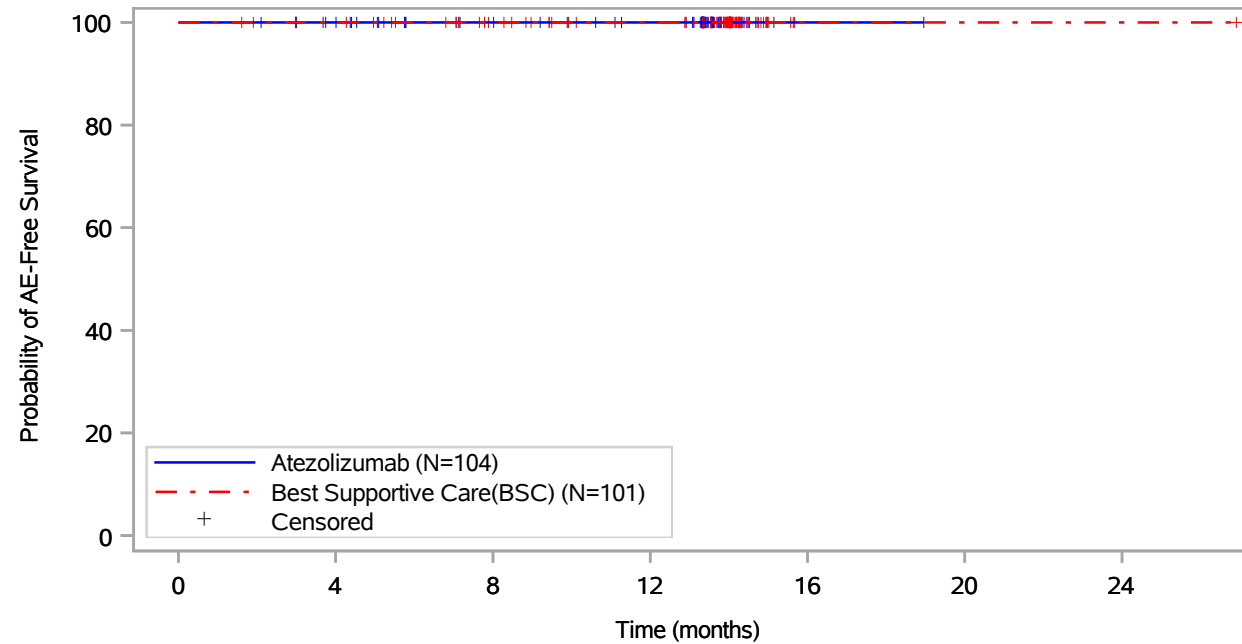
Patients at risk							
Atezolizumab (N=104)	104	97	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...s/ACE_OS_IA/prod/output/g_km_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:15

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Grade \geq 3
STUDY: GO29527



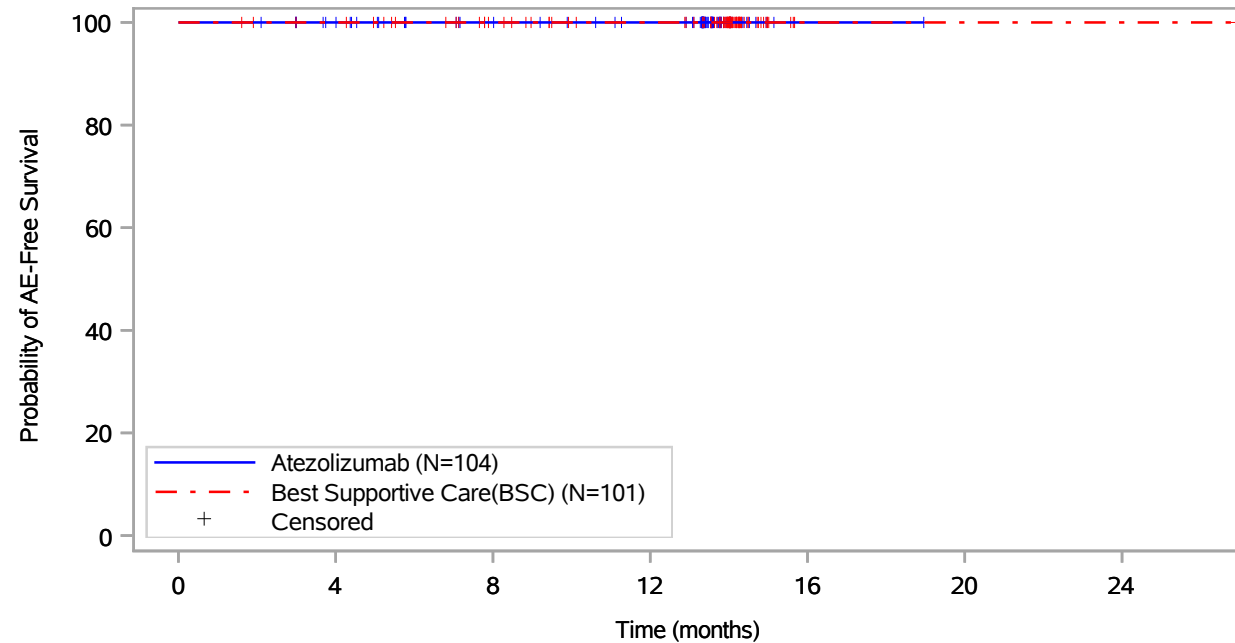
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMOT35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:16

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Ocular Inflammatory Toxicity Serious
STUDY: GO29527



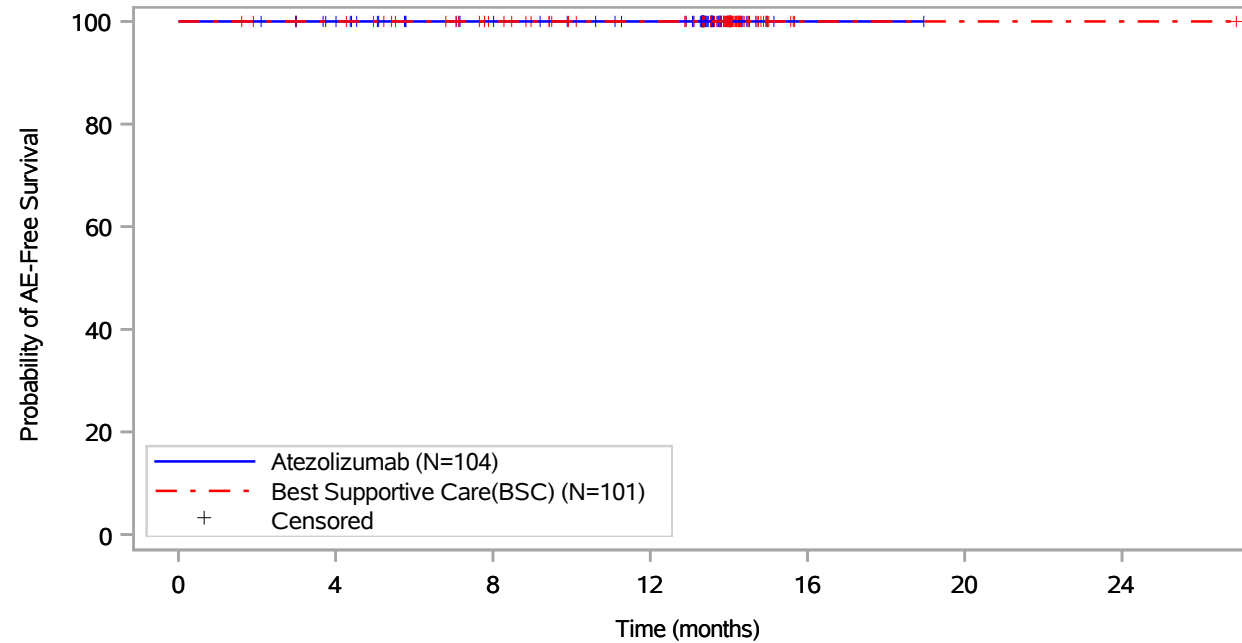
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:18

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Autoimmune Hemolytic Anemia
STUDY: GO29527



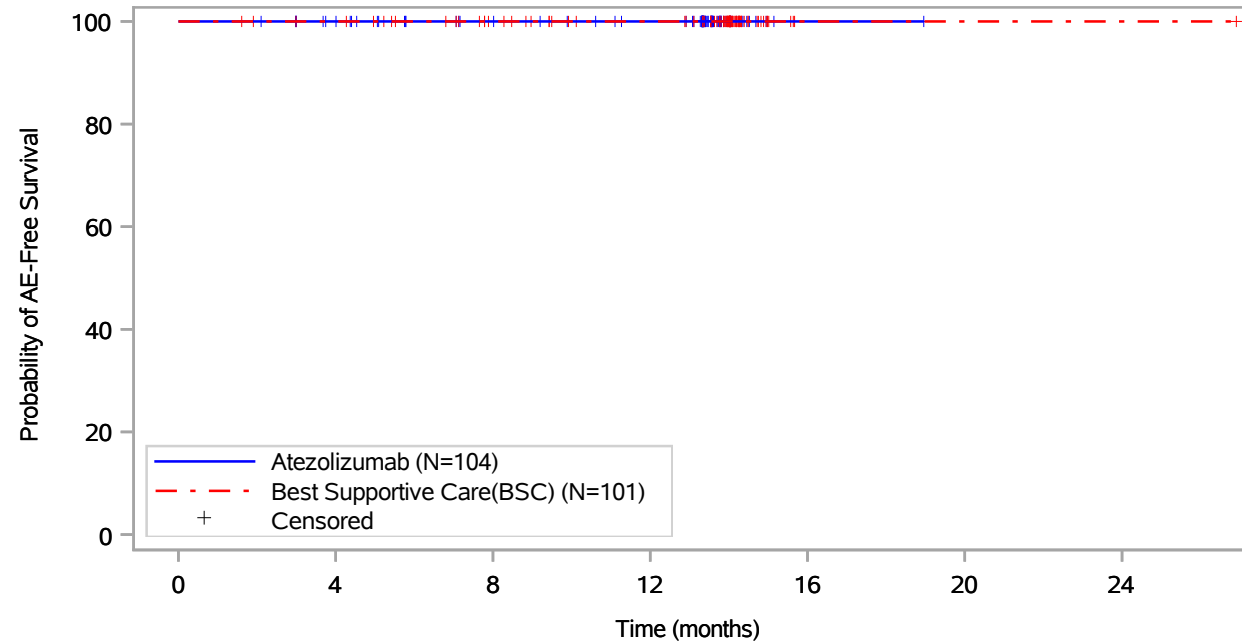
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..\ACE_OS_IA/prod/output/g_km_TTAHA_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Autoimmune Hemolytic Anemia Grade \geq 3
STUDY: GO29527



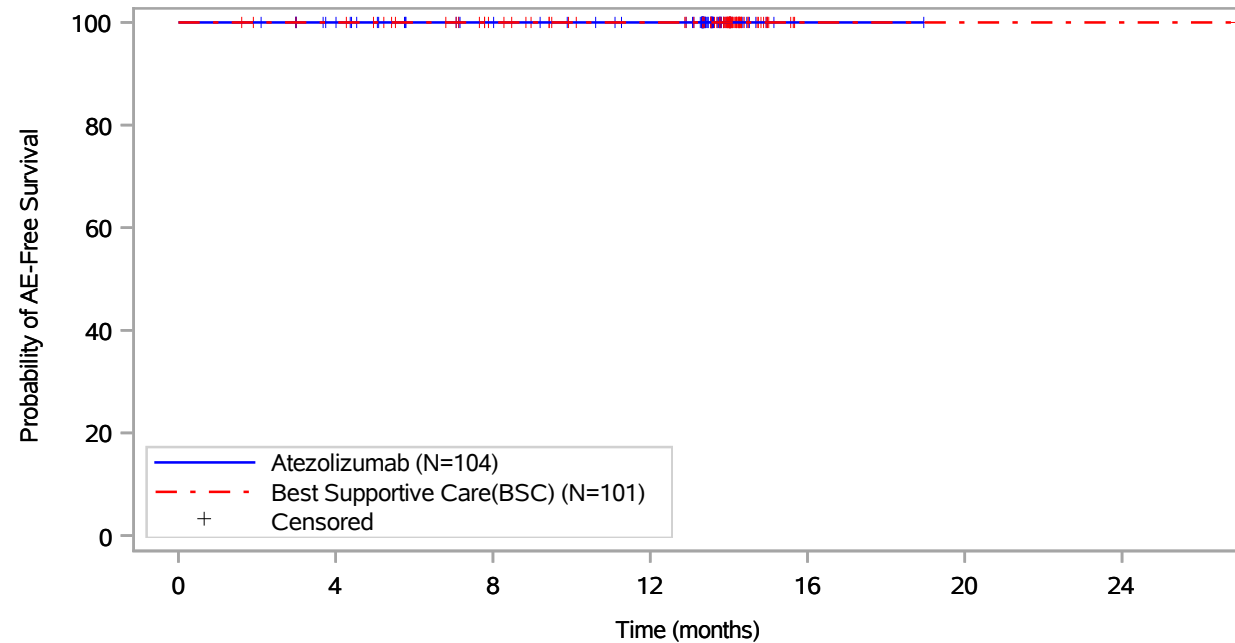
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTAHA35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Autoimmune Hemolytic Anemia Serious
STUDY: GO29527



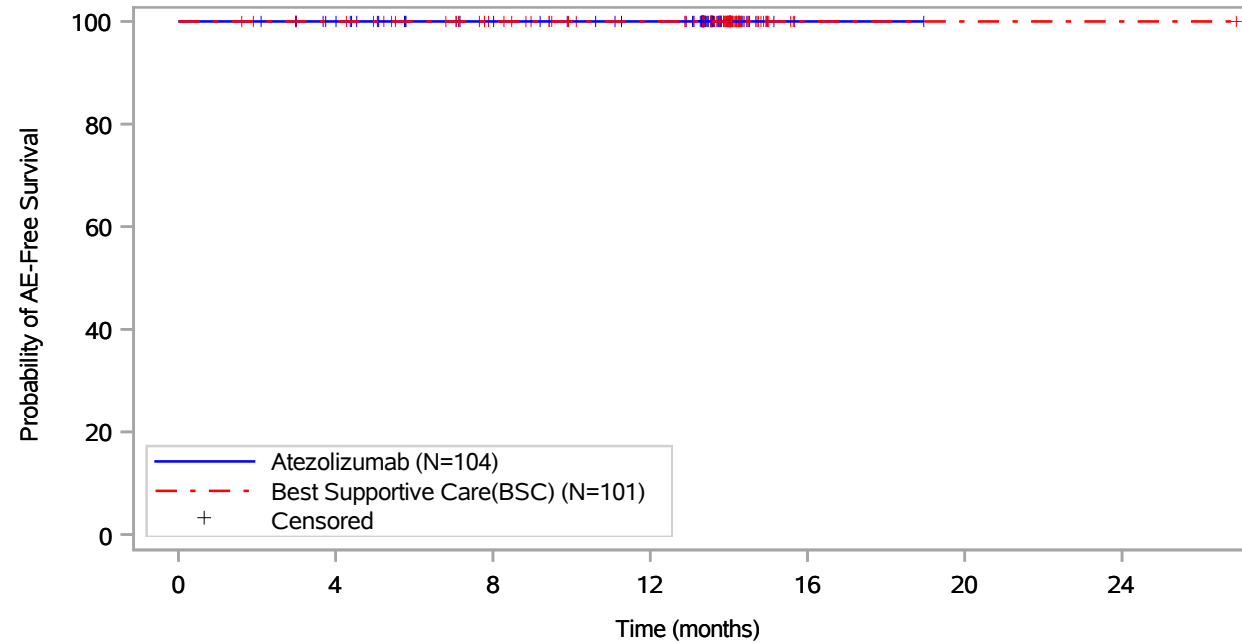
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTAHAS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency
STUDY: GO29527



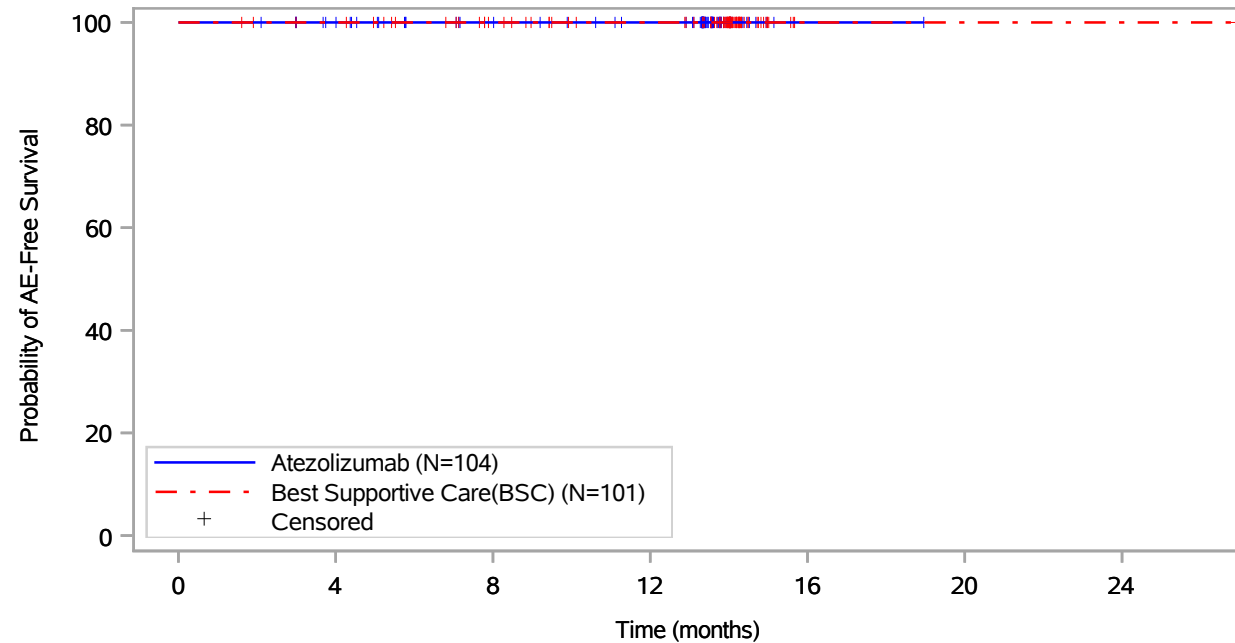
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: .../ACE_OS_IA/prod/output/g_km_TTIMAI_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:11

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency Grade \geq 3
STUDY: GO29527



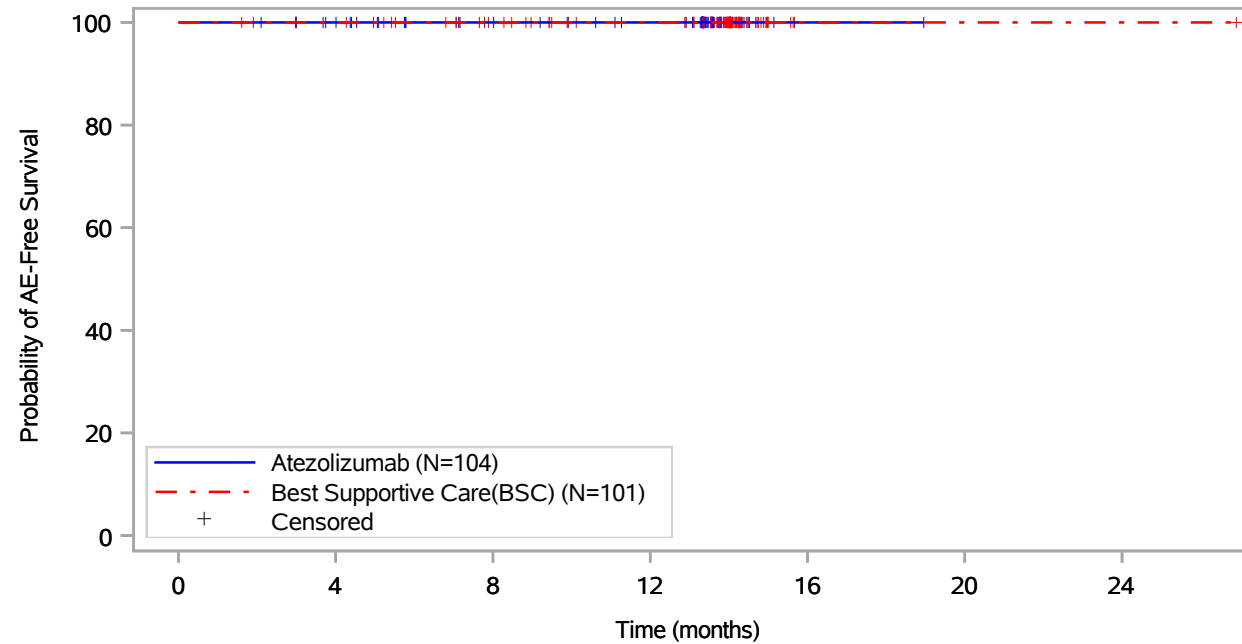
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TT1MAI35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:13

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Adrenal insufficiency Serious
STUDY: GO29527



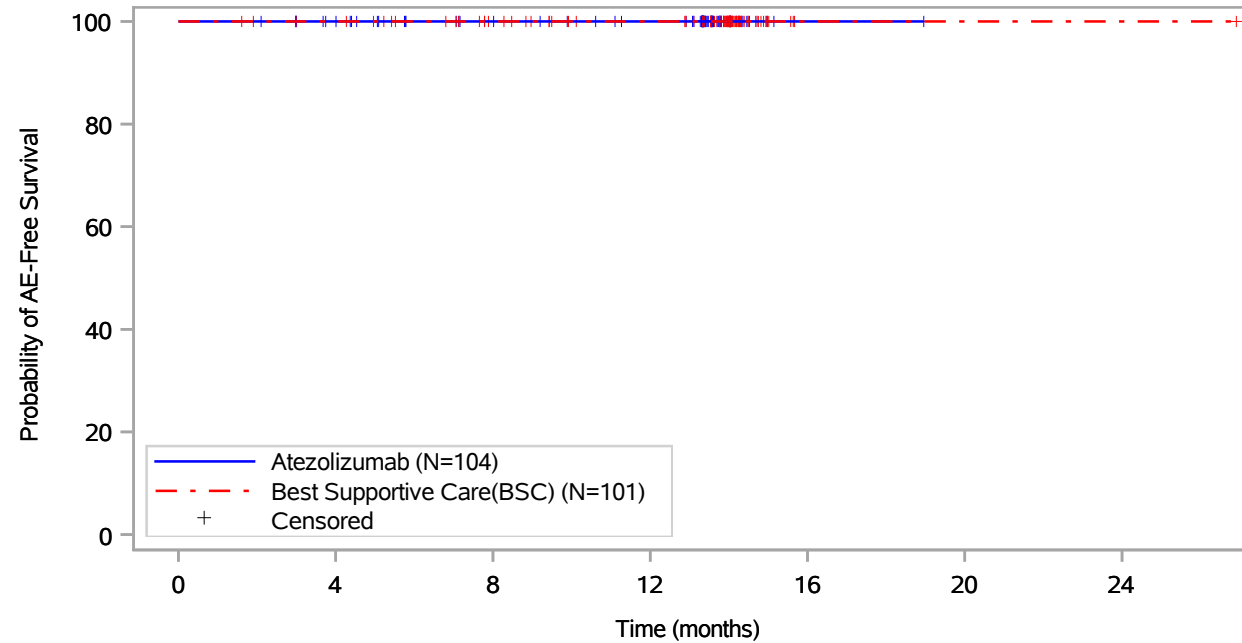
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTAIMAIS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:14

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Diabetes mellitus
STUDY: GO29527



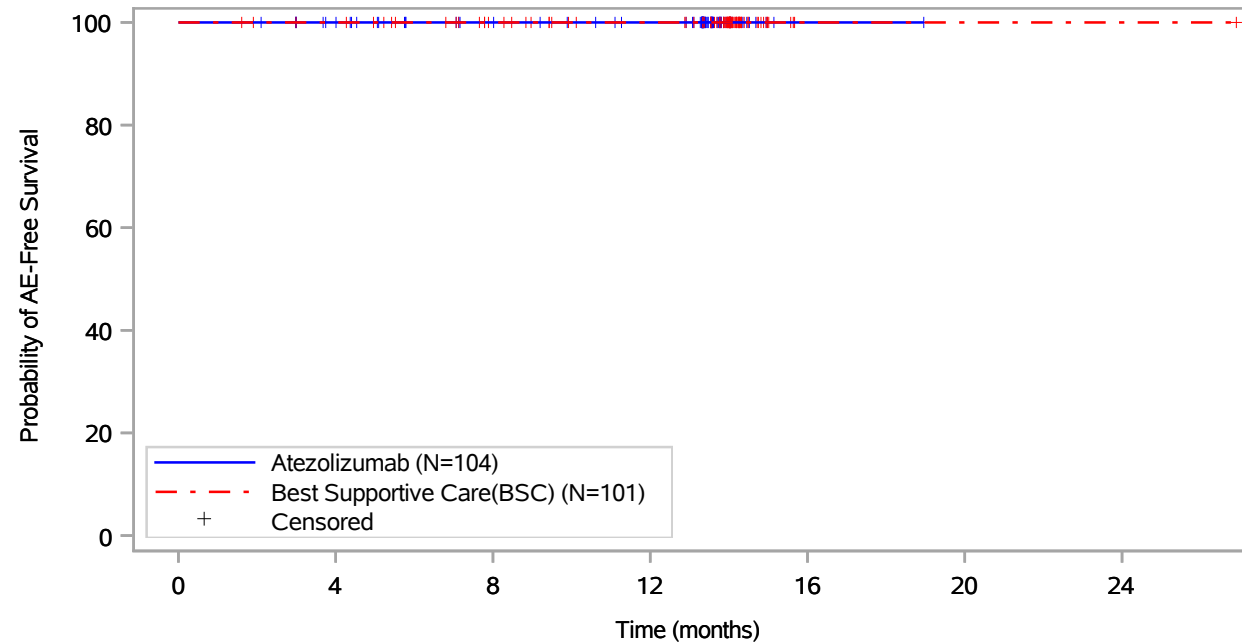
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_OS_IA/prod/output/g_km_TTMDM_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:37

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Diabetes mellitus Grade \geq 3
STUDY: GO29527



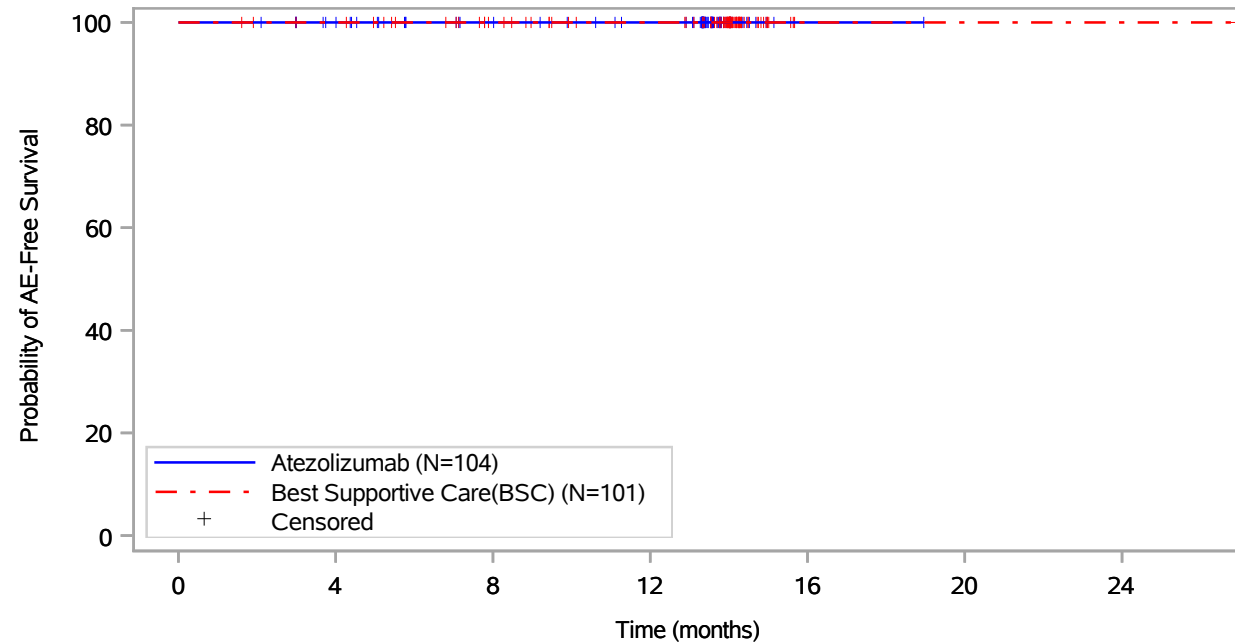
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTMDM35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:39

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Diabetes mellitus Serious
STUDY: GO29527



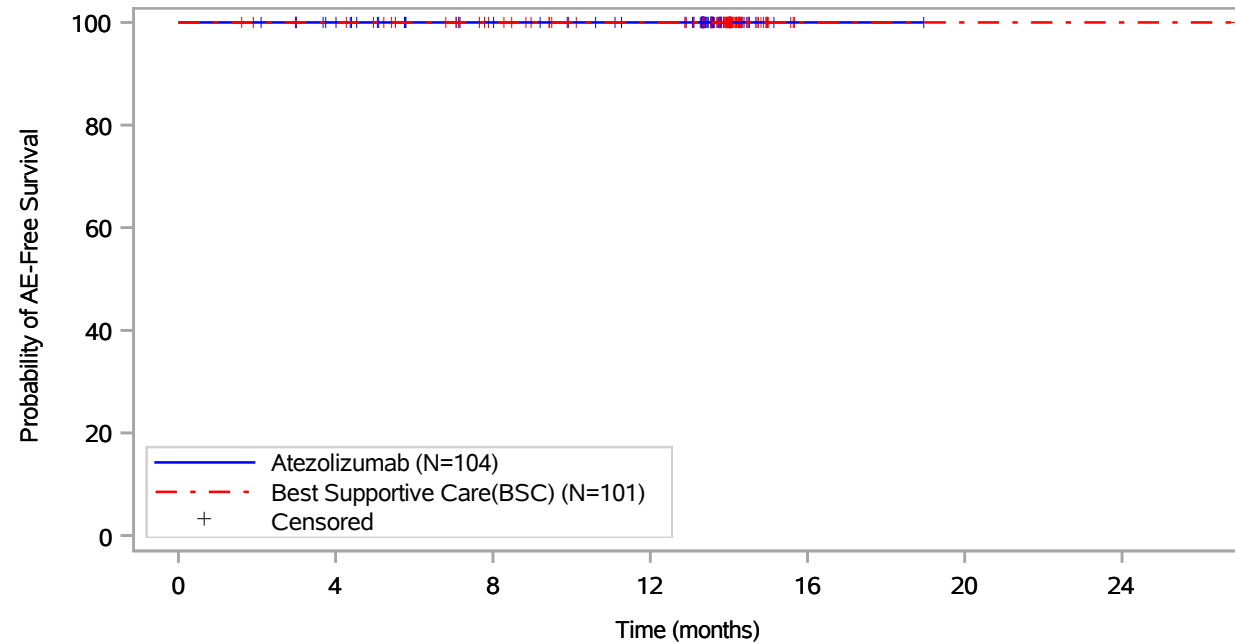
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMDMS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypophysitis
STUDY: GO29527



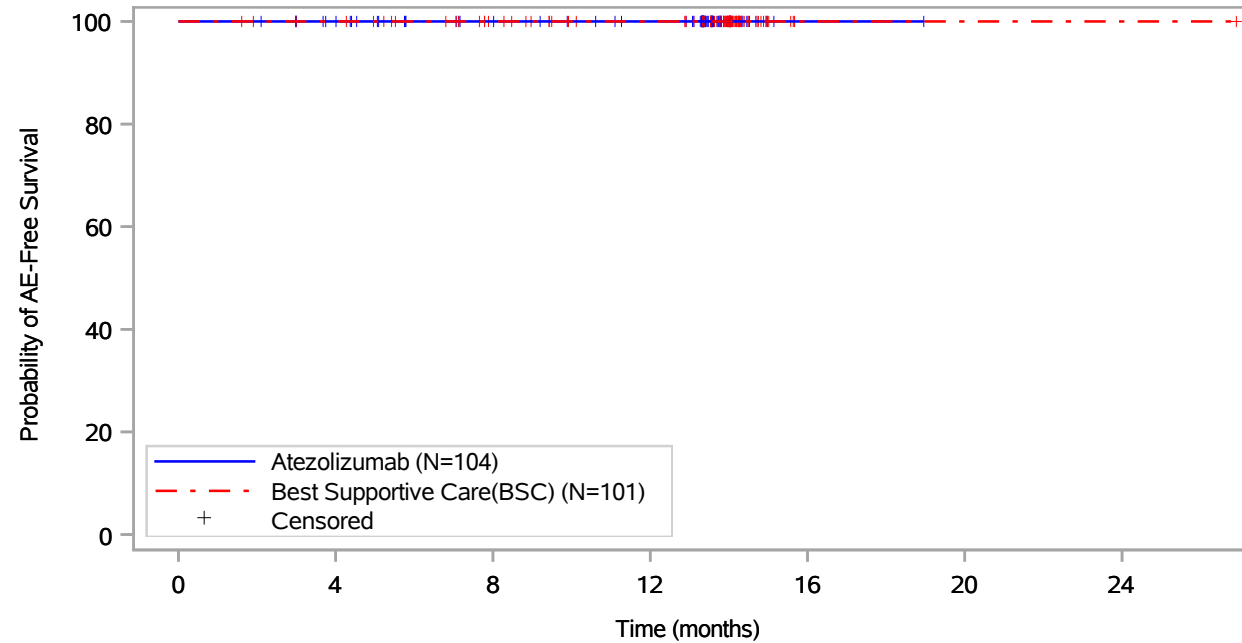
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: .../ACE_OS_IA/prod/output/g_km_TT1MLH_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:25

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypophysitis Grade >= 3
STUDY: GO29527



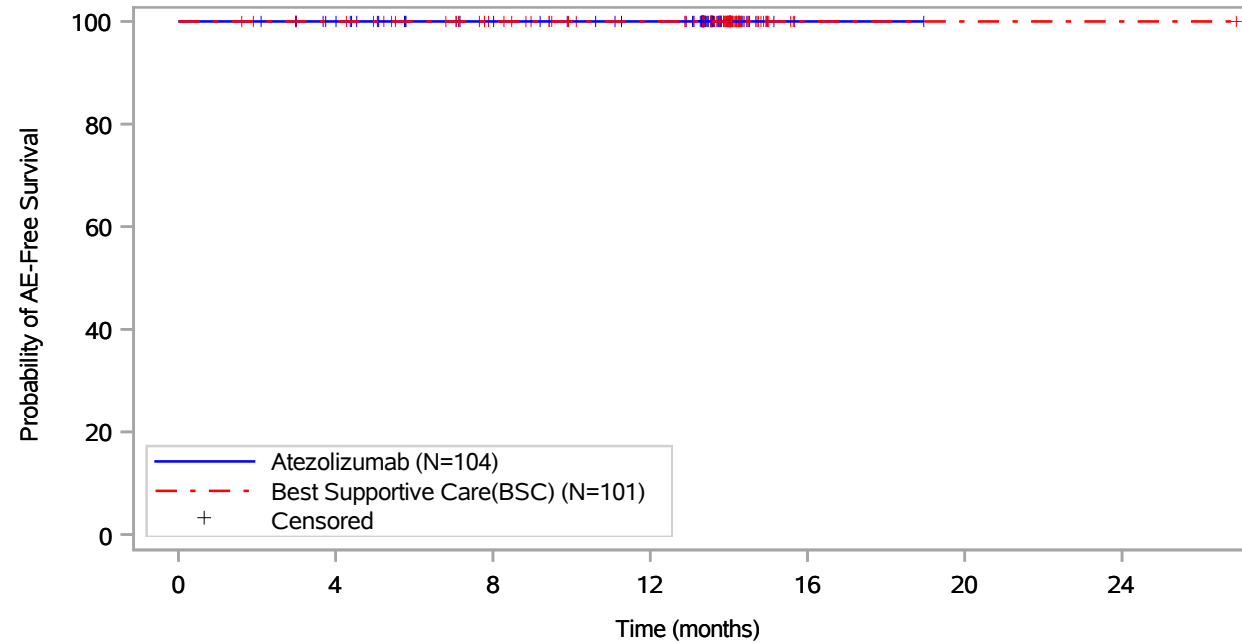
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TT1MLH35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:27

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Hypophysitis Serious
STUDY: GO29527



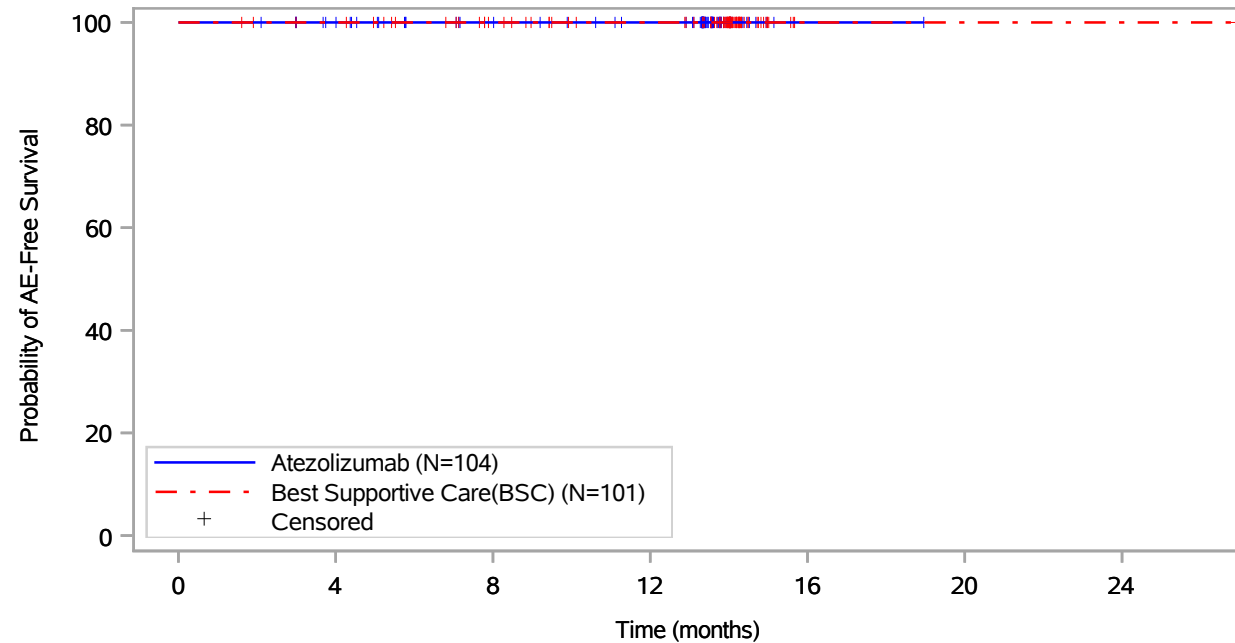
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTILHS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myocarditis
STUDY: GO29527



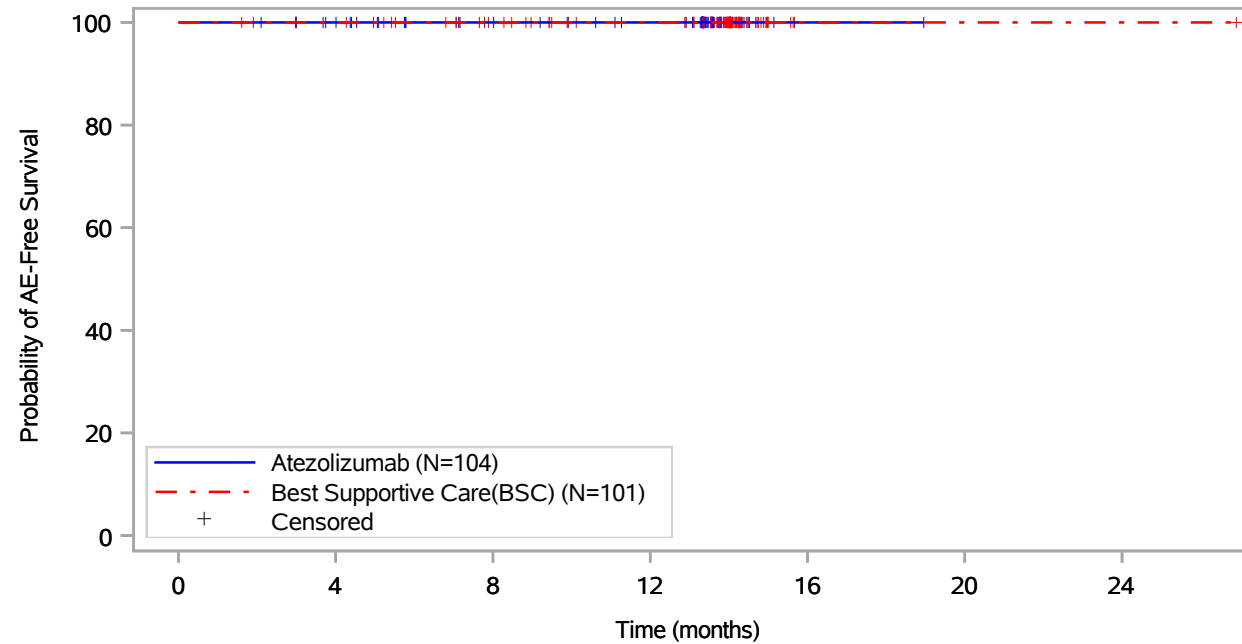
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_OS_IA/prod/output/g_km_TTIMMC_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myocarditis Grade >= 3
STUDY: GO29527



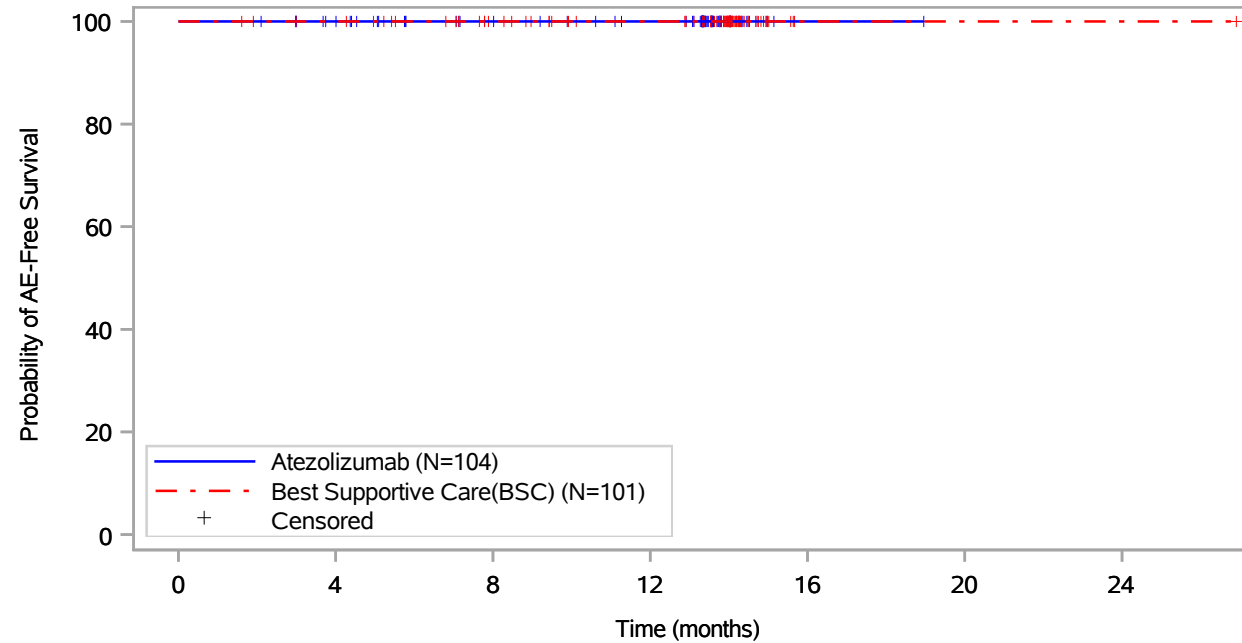
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMMC35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:32

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myocarditis Serious
STUDY: GO29527



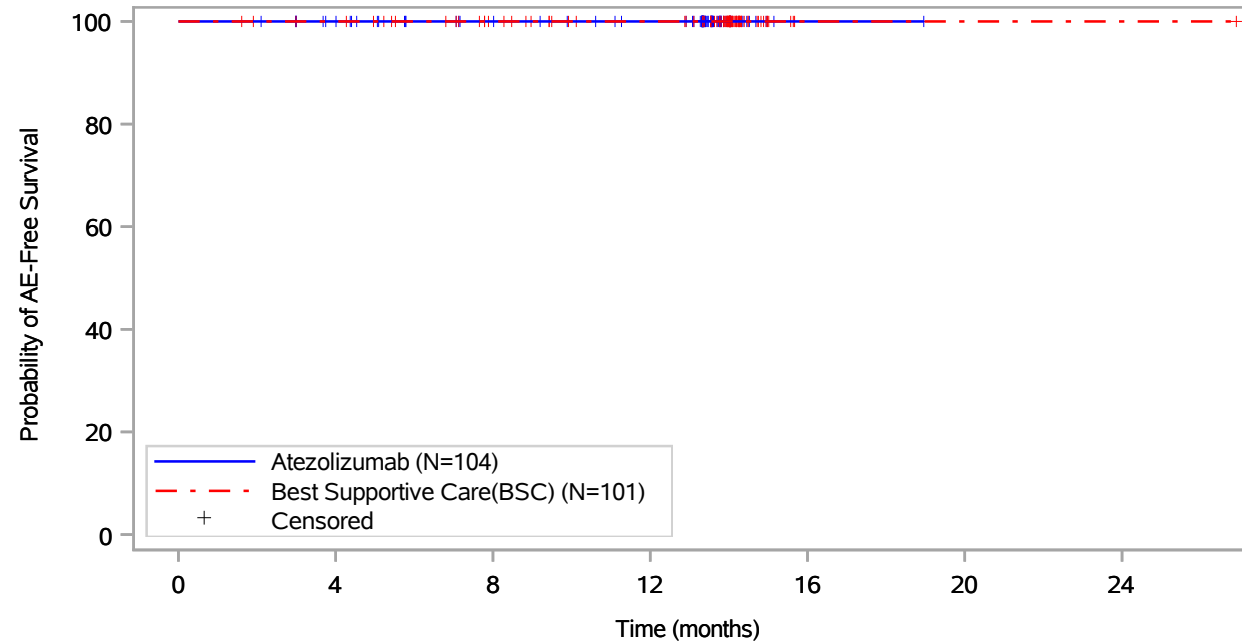
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMCS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis
STUDY: GO29527



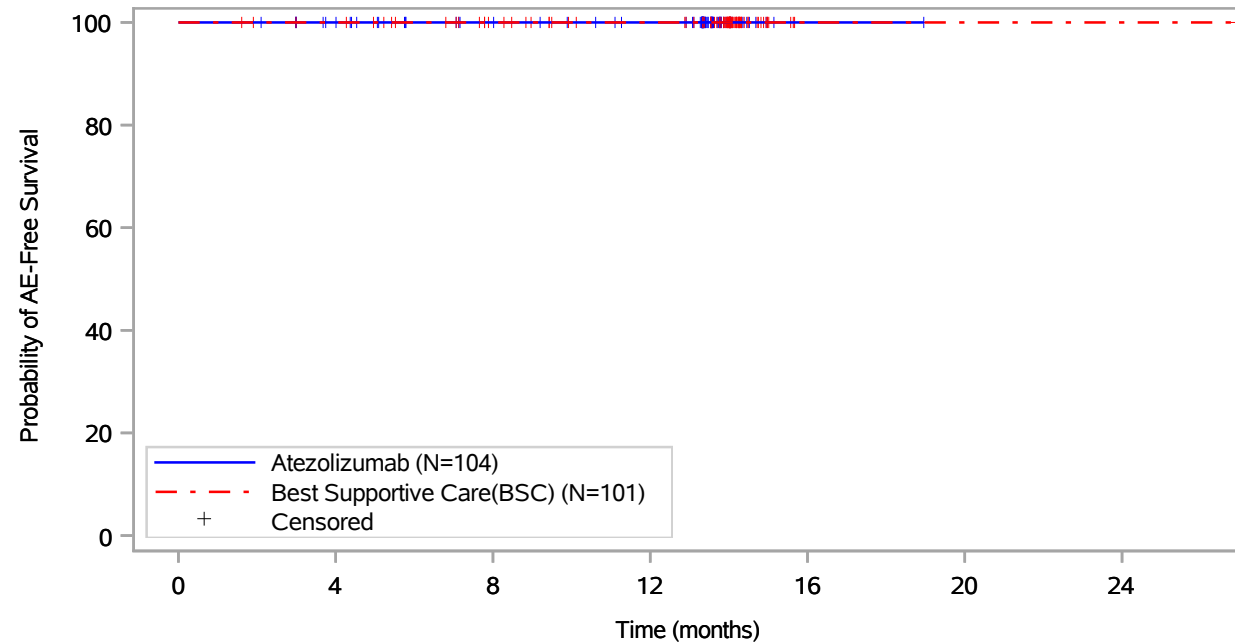
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMG_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:31

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis Grade \geq 3
STUDY: GO29527



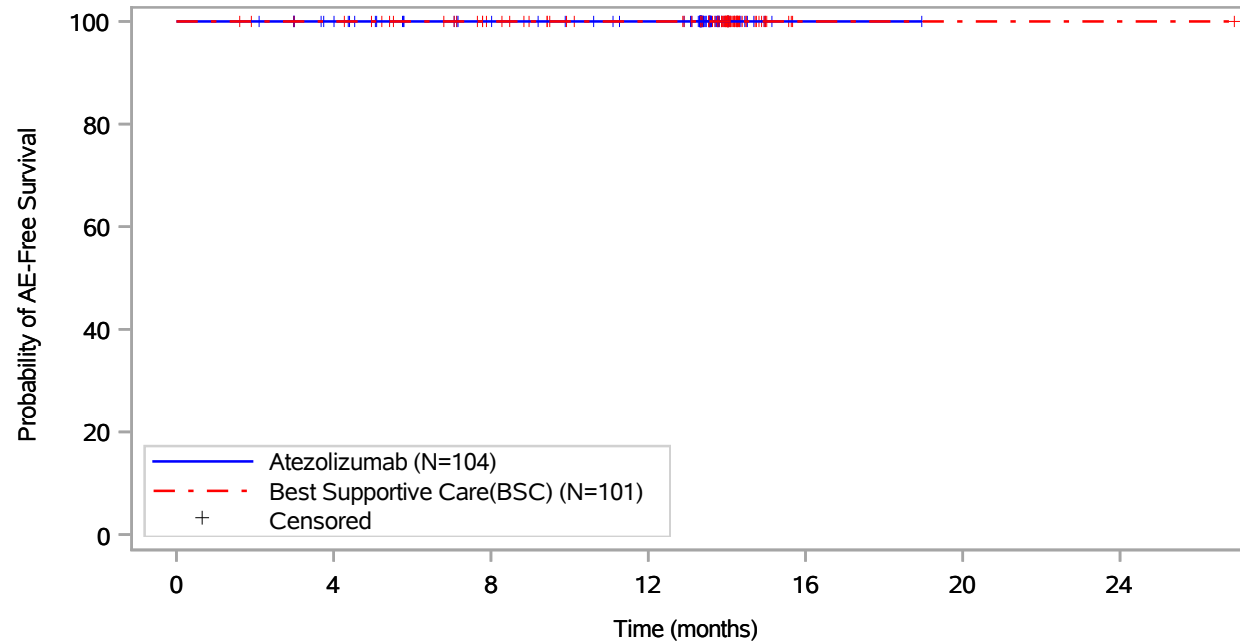
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMG35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:33

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myasthenia Gravis Serious
STUDY: GO29527



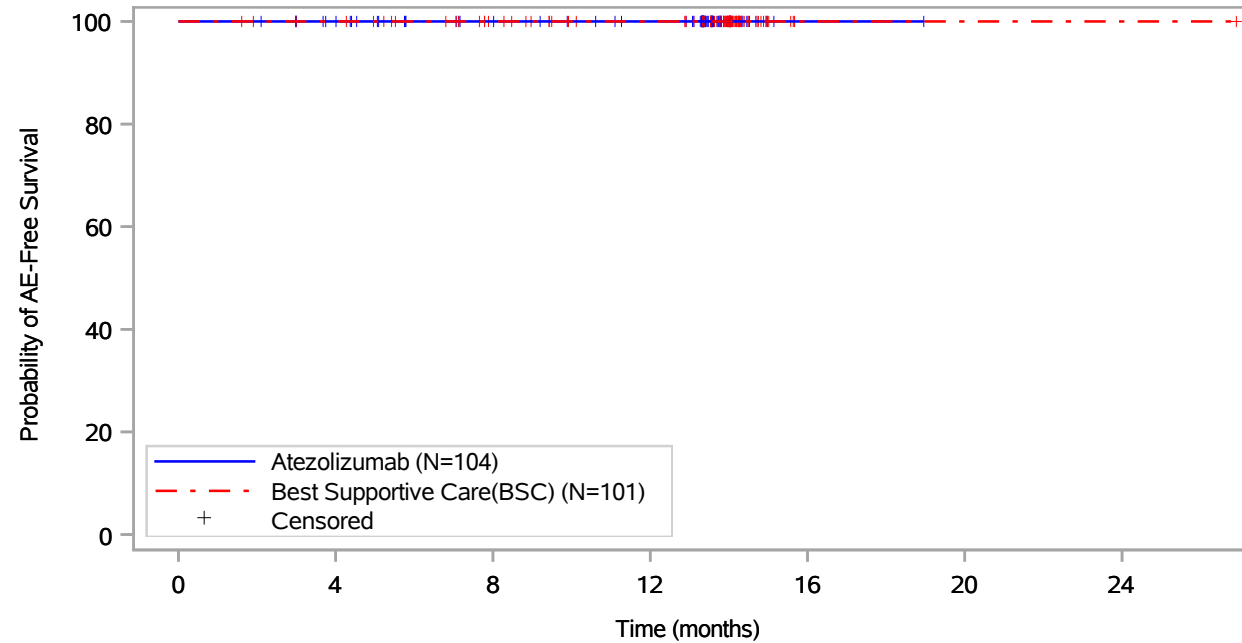
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMGS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 15:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myositis
STUDY: GO29527



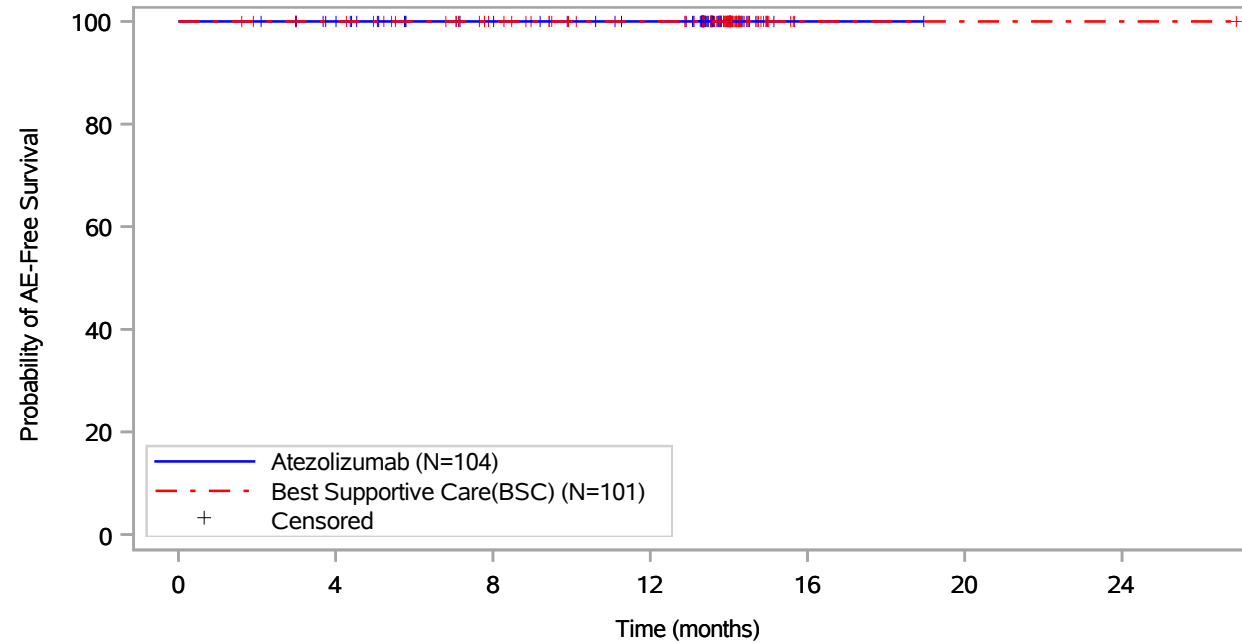
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_OS_IA/prod/output/g_km_TTIMMY_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:42

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myositis Grade \geq 3
STUDY: GO29527



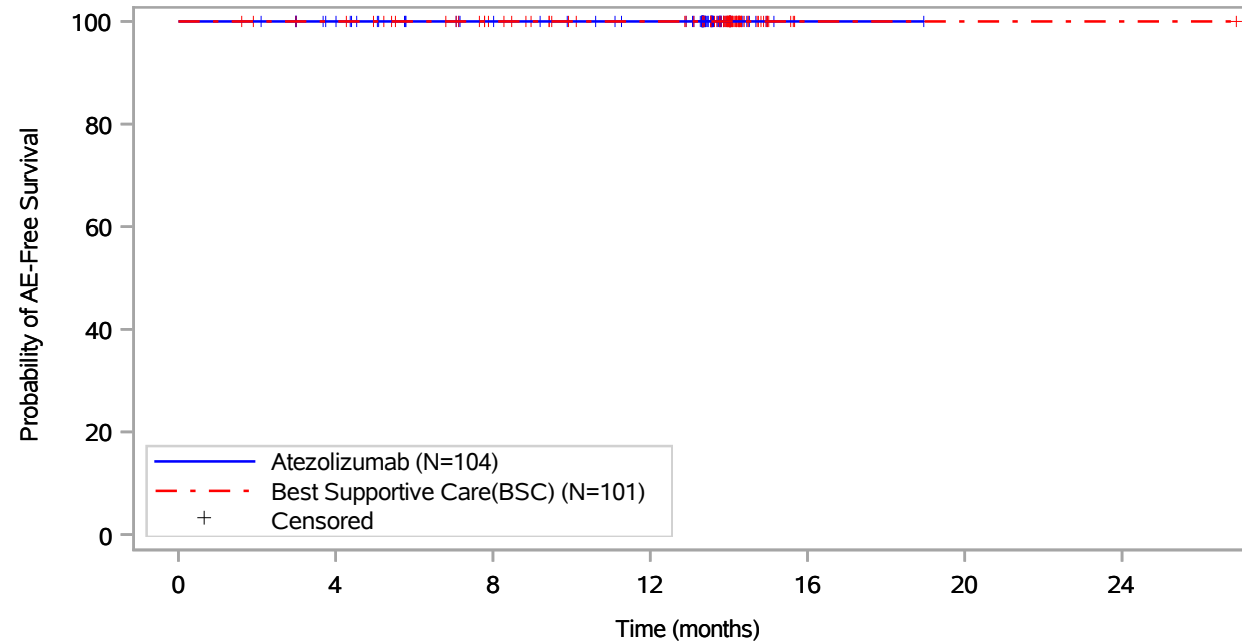
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMMY35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Myositis Serious
STUDY: GO29527



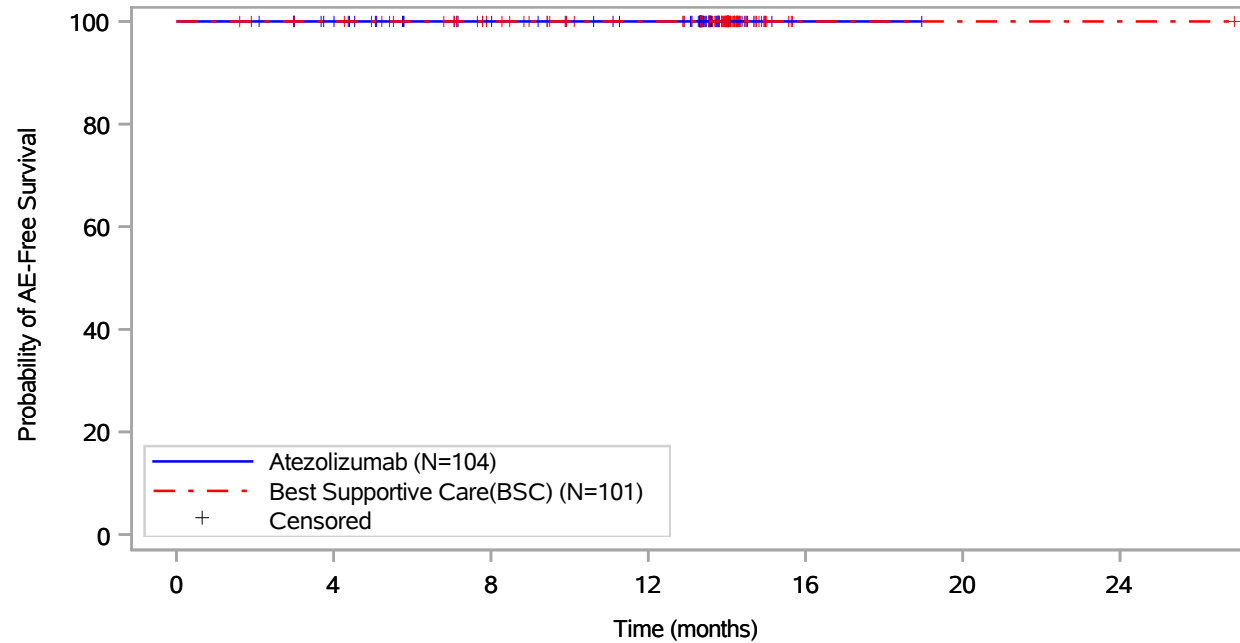
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMMYS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:46

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Nephritis
STUDY: GO29527



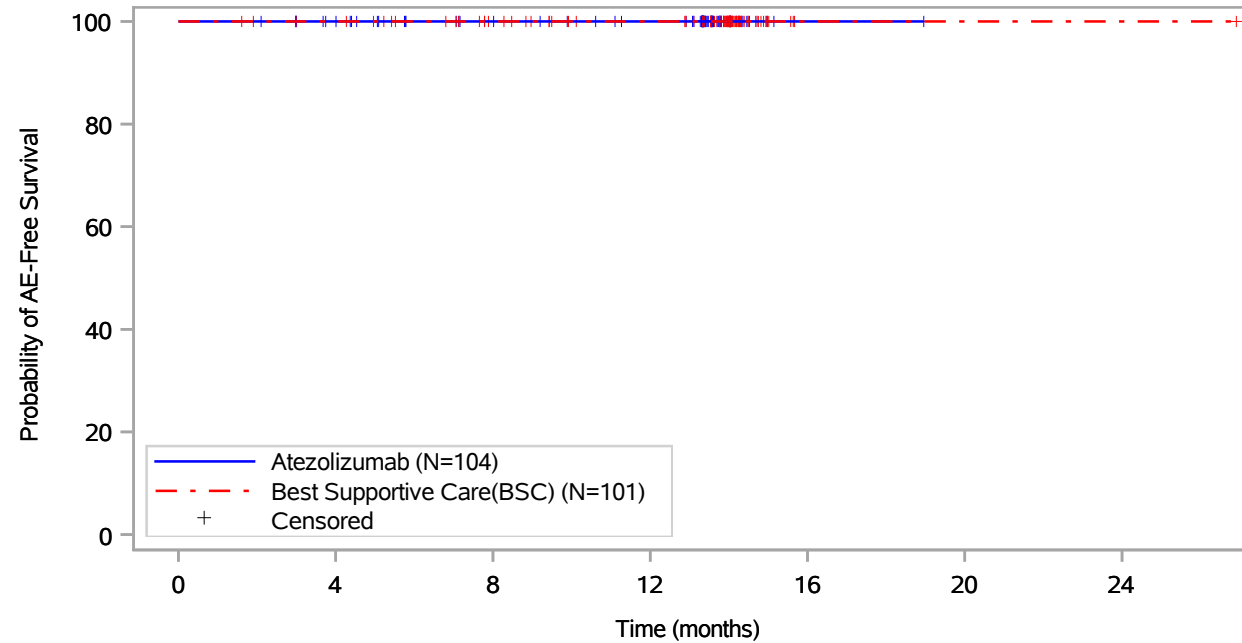
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..s/ACE_OS_IA/prod/output/g_km_TTIMNP_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:53

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Nephritis Grade \geq 3
STUDY: GO29527



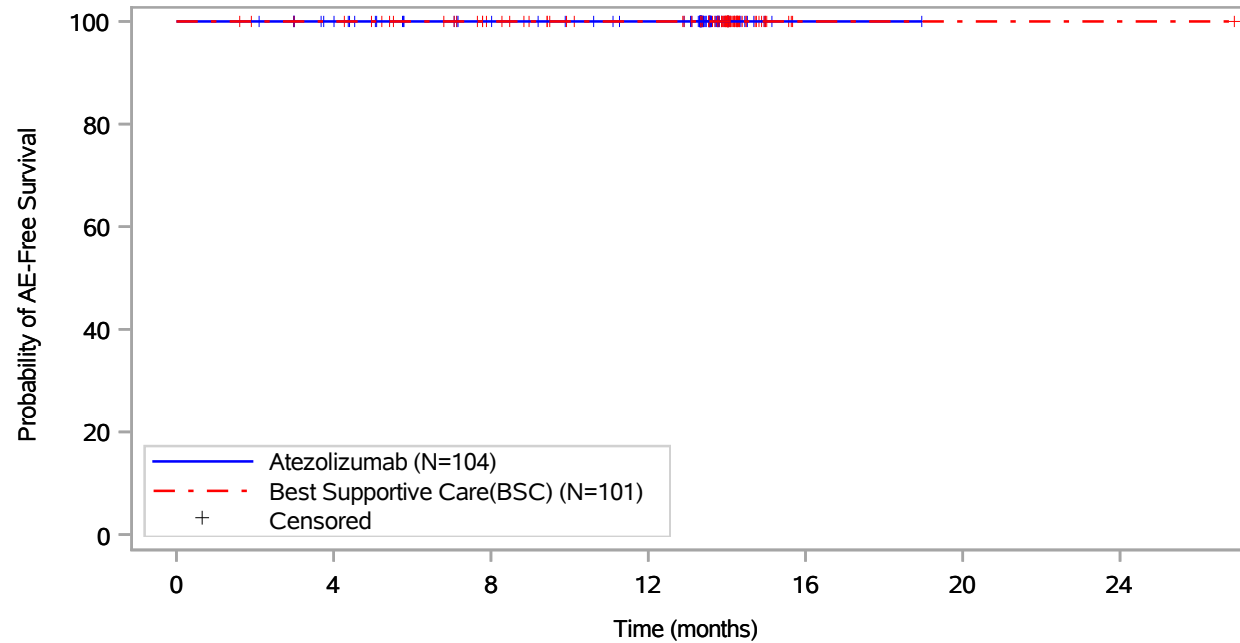
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMNP35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:55

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Nephritis Serious
STUDY: GO29527



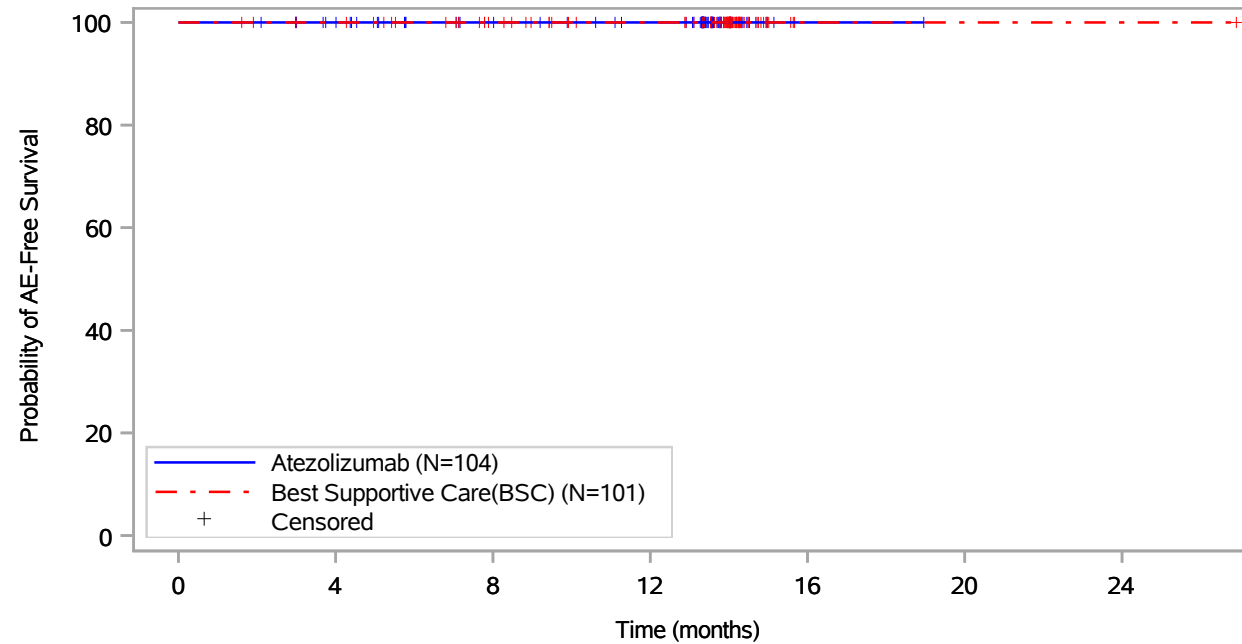
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMNPS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:57

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pancreatitis
STUDY: GO29527



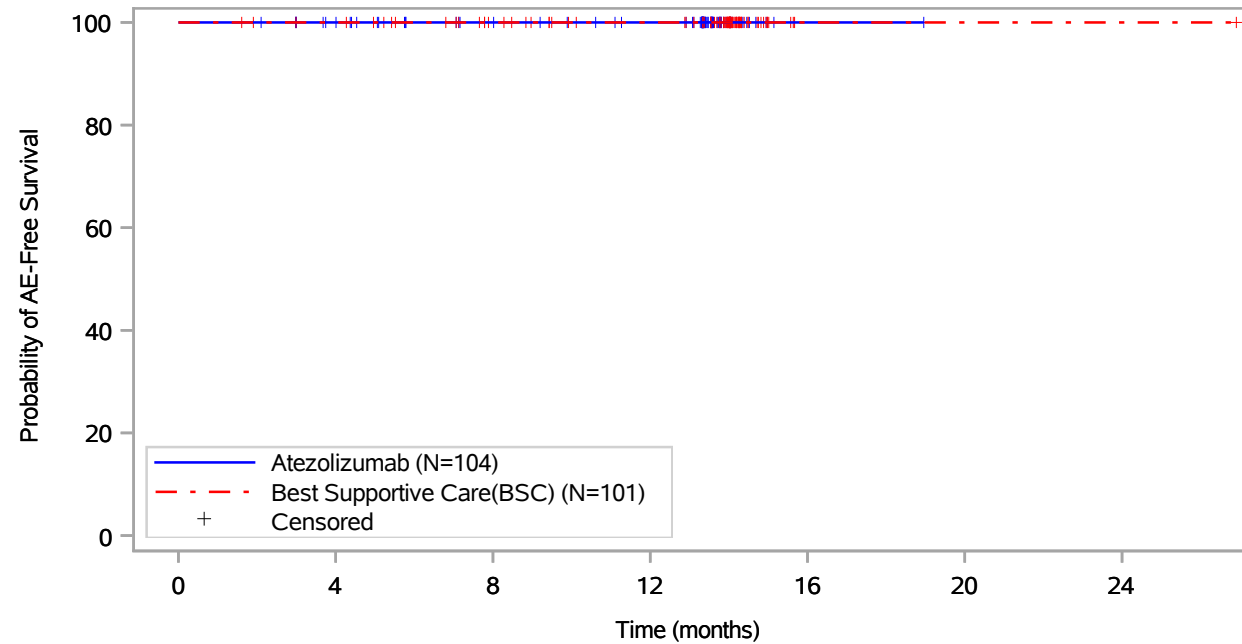
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...s/ACE_OS_IA/prod/output/g_km_TTIMPC_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:32

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pancreatitis Grade >= 3
STUDY: GO29527



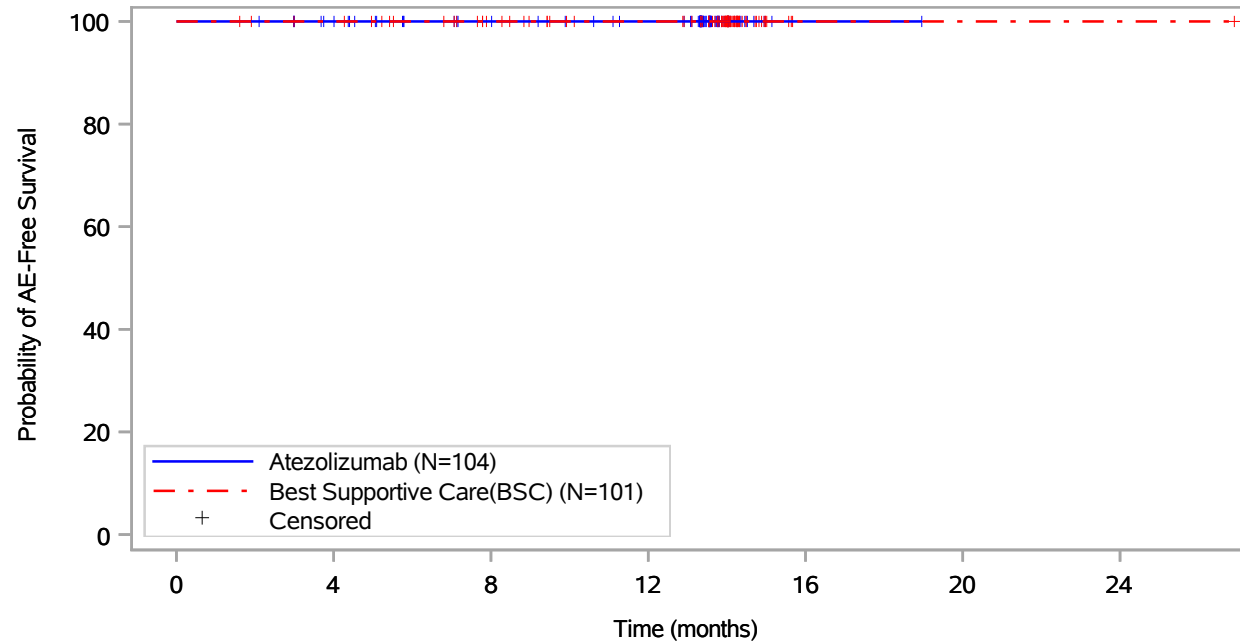
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMPC35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:34

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Pancreatitis Serious
STUDY: GO29527



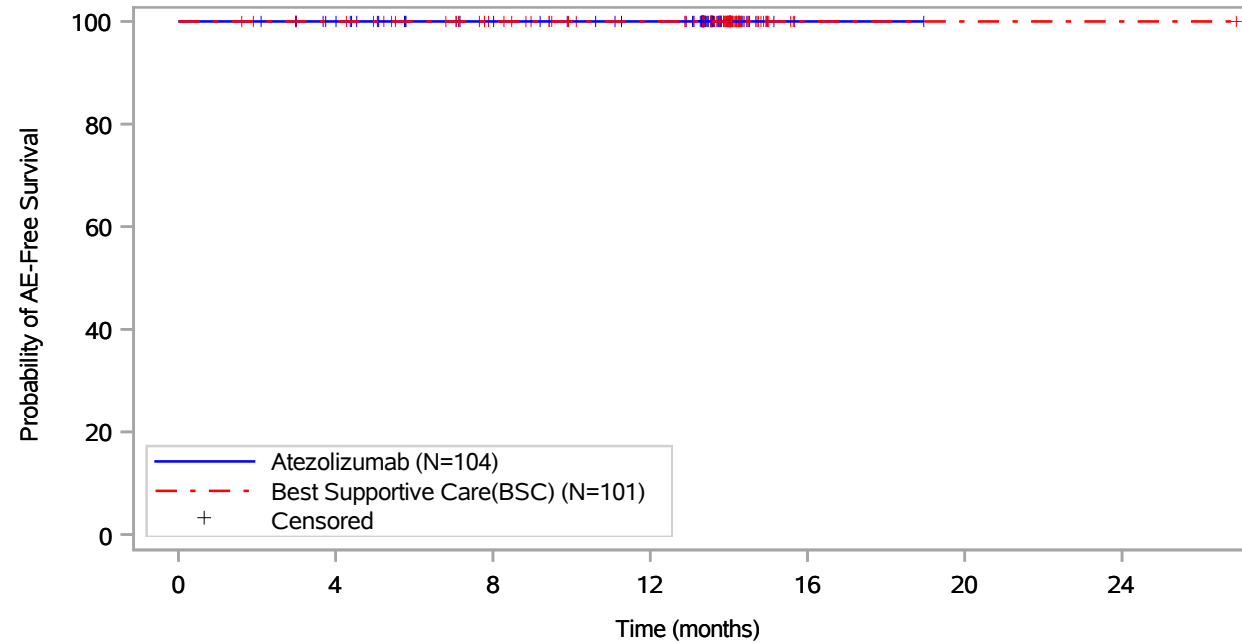
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMPCS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:35

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Vasculitis
STUDY: GO29527



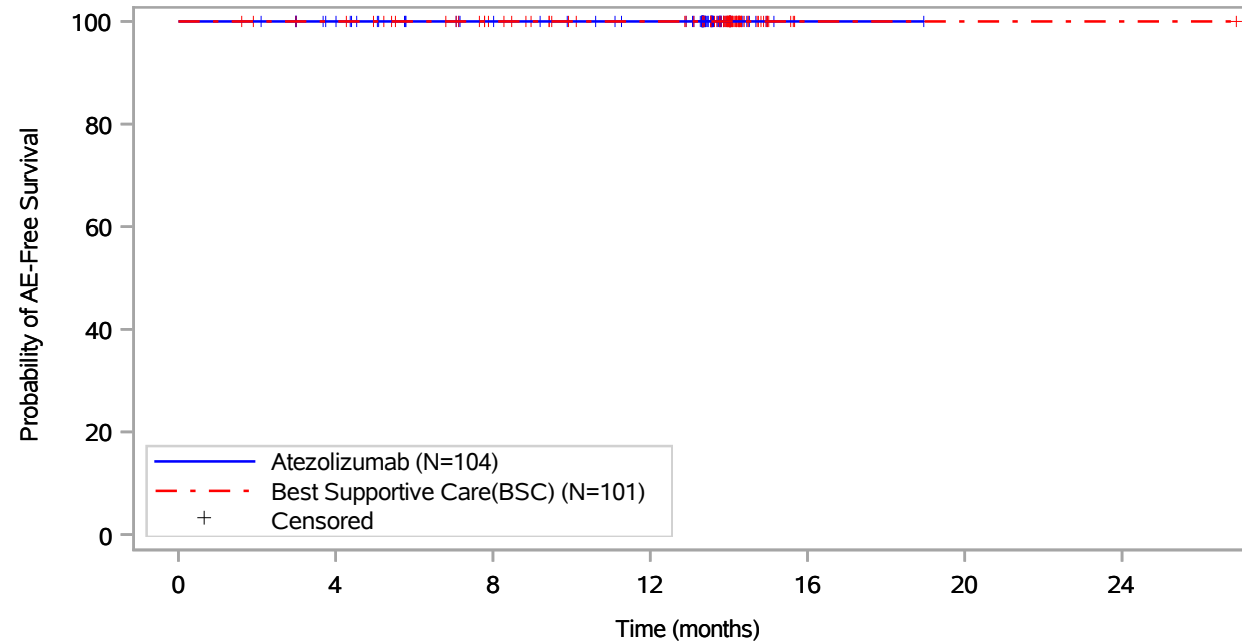
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMVS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:19

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Vasculitis Grade \geq 3
STUDY: GO29527



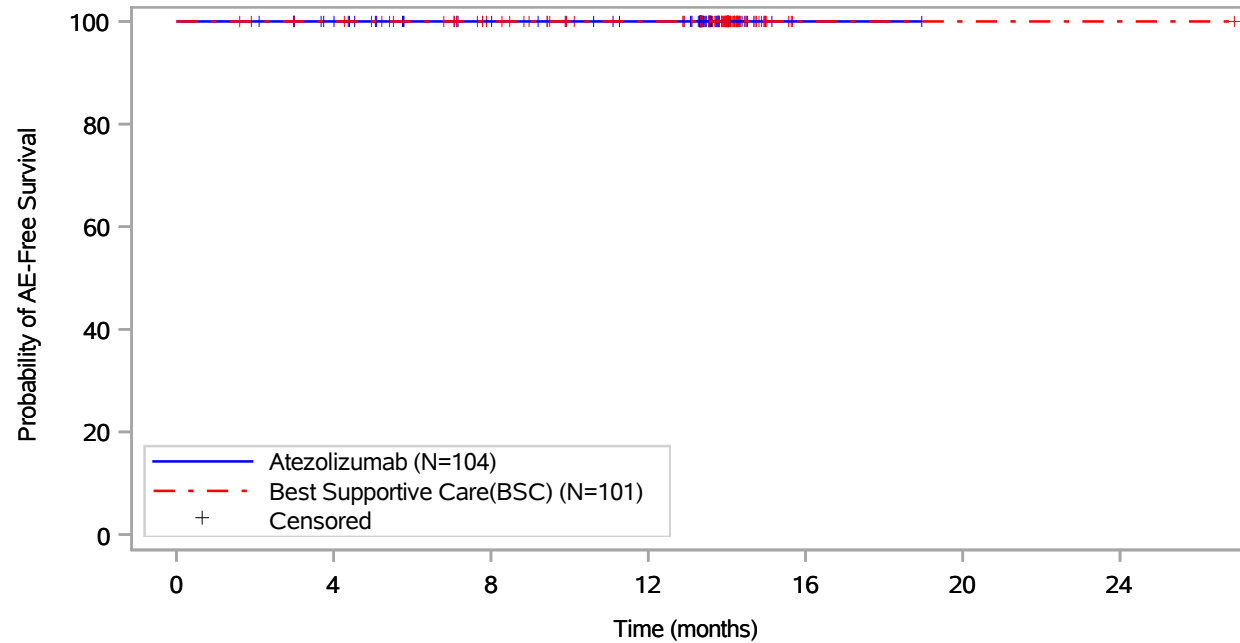
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTIMVS35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:21

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Immune-Mediated Vasculitis Serious
STUDY: GO29527



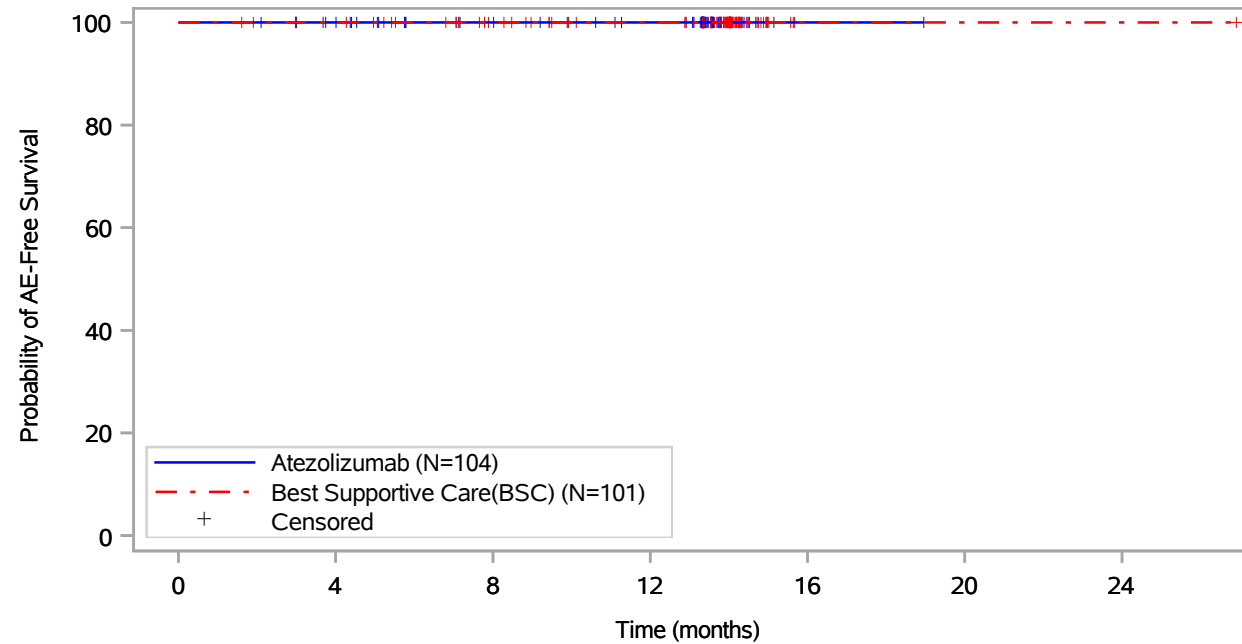
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIMVSS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 13:23

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Infusion-Related Reactions
STUDY: GO29527



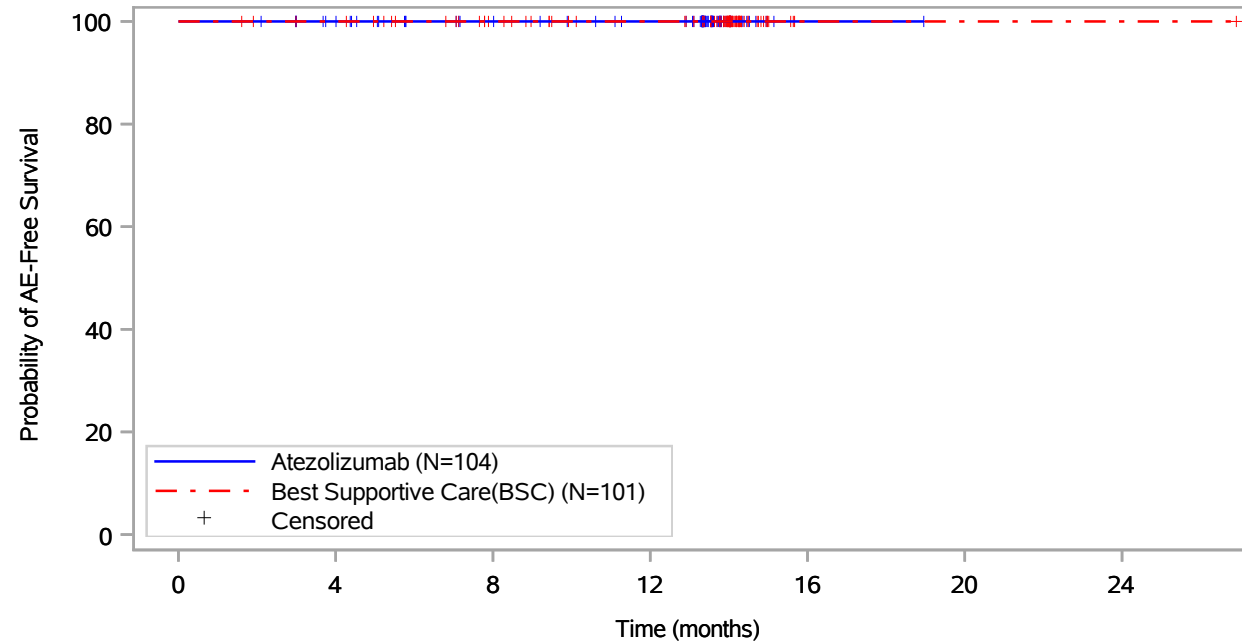
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..\ACE_OS_IA\prod\output\g_km_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:26

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Infusion-Related Reactions Grade >= 3
STUDY: GO29527



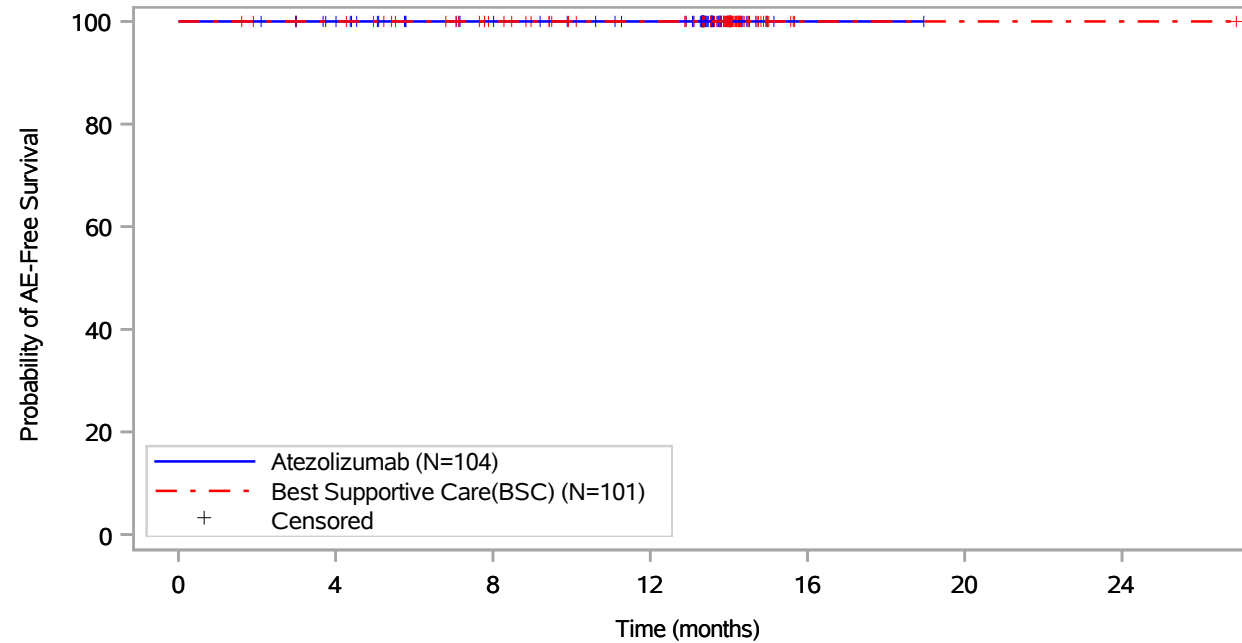
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ../ACE_OS_IA/prod/output/g_km_TTIRR35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:28

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Infusion-Related Reactions Serious
STUDY: GO29527



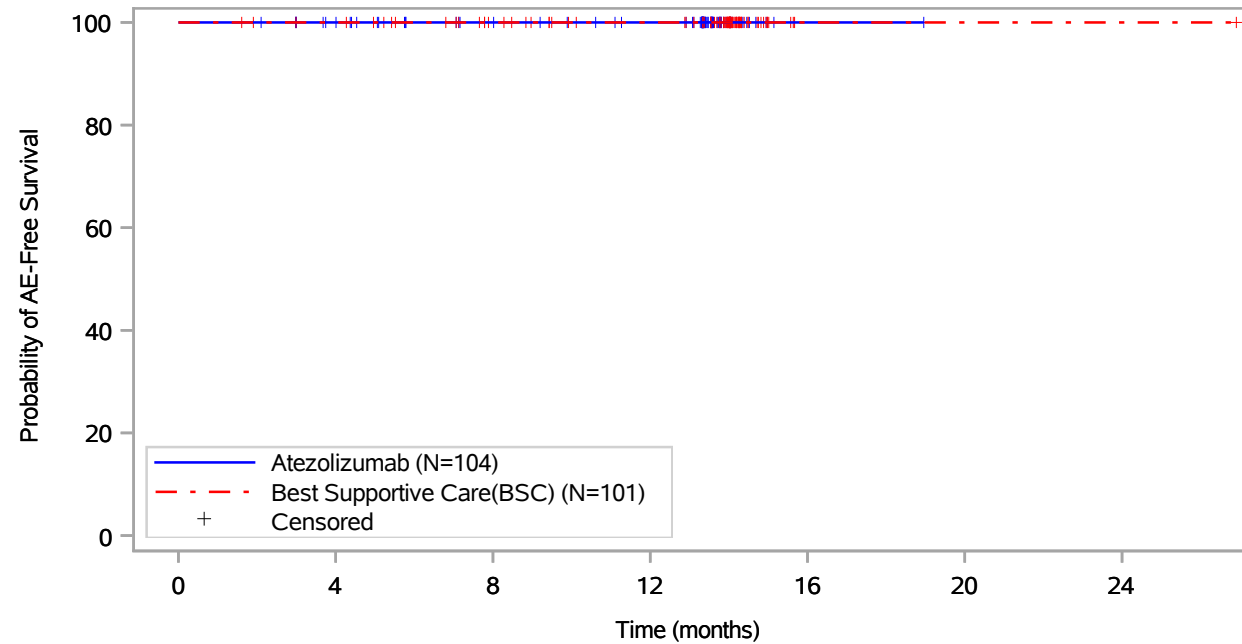
Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: .../ACE_OS_IA/prod/output/g_km_TTIRRS_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:30

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Rhabdomyolysis
STUDY: GO29527



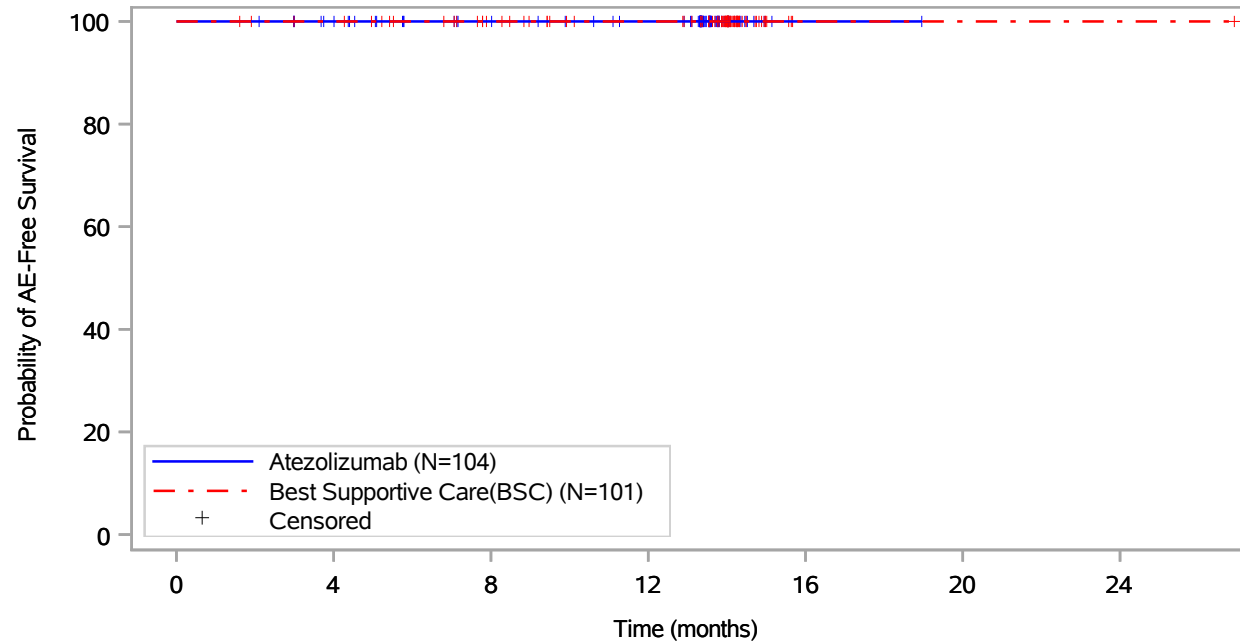
Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)		104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)		101	98	86	77	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)		0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)		0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ...s/ACE_OS_IA/prod/output/g_km_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:47

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Rhabdomyolysis Grade >= 3
STUDY: GO29527



Patients at risk		0	4	8	12	16	20	24
Atezolizumab (N=104)	104	97	85	79	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1	1
Patients censored		0	4	8	12	16	20	24
Atezolizumab (N=104)	0	7	19	25	103	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/g_km.sas
 Output: ..ACE_OS_IA/prod/output/g_km_TTRHAB35_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.pdf
 27JUN2022 12:49

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Spezifische Verträglichkeit

Outcome

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: All Patients
 MODEL: --
 STUDY: GO29527
 Outcome of Adverse Events of Special Interest

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care(BSC) (N=101)																	
	Total	RECOVERED/R ESOLVED		RECOVERED/R ESOLVED WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/R ESOLVED		RECOVERED/R ESOLVED WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING			
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Immune-Mediated Hepatitis																																
All	25	22	88,0	1	4,0	1	4,0	0	0,0	1	4,0	0	0,0	0	0,0	8	6	75,0	0	0,0	2	25,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	15	14	93,3	0	0,0	0	0,0	0	0,0	1	6,7	0	0,0	0	0,0	8	6	75,0	0	0,0	2	25,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	3	1	33,3	1	33,3	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	7	7	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hepatitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Hypothyroidism																																
All	19	7	36,8	0	0,0	10	52,6	0	0,0	2	10,5	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	11	7	63,6	0	0,0	3	27,3	0	0,0	1	9,1	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	0	0,0	0	0,0	7	87,5	0	0,0	1	12,5	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hypothyroidism																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Hyperthyroidism																																
All	5	5	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	1	50,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hyperthyroidism																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Adrenal insufficiency																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Adrenal insufficiency																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Pneumonitis																																
All	6	4	66,7	0	0,0	0	0,0	0	0,0	1	16,7	1	16,7	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	2	1	50,0	0	0,0	0	0,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	3	2	66,7	0	0,0	0	0,0	0	0,0	0	0,0	1	33,3	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Pneumonitis																																
All	2	1	50,0	0	0,0	0	0,0	0	0,0	1	50,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	1	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	100,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Vollständige Darstellung relevanter Ergebnisse

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care(BSC) (N=101)																	
	Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING			
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Grade 4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Colitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Colitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Guillain-Barre Syndrome																																
All	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Guillain-Barre Syndrome																																
All	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Myasthenia Gravis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Myasthenia Gravis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Meningoencephalitis																																
All	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Meningoencephalitis																																
All	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Infusion-Related Reactions																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Infusion-Related Reactions																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Pancreatitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Pancreatitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Diabetes mellitus																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Diabetes mellitus																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Myositis																																

Vollständige Darstellung relevanter Ergebnisse

Category of Adverse Events Grade	Atezolizumab (N=104)														Best Supportive Care (BSC) (N=101)																	
	Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING			
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Myositis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Rhabdomyolysis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Rhabdomyolysis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Nephritis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Nephritis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Rash																																
All	26	19	73,1	1	3,8	6	23,1	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	17	15	88,2	1	5,9	1	5,9	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 2	8	3	37,5	0	0,0	5	62,5	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Rash																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Meningitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Meningitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Encephalitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Encephalitis																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Ocular Inflammatory Toxicity																																
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Ocular Inflammatory Toxicity																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Vasculitis																																

Vollständige Darstellung relevanter Ergebnisse

Category of Adverse Events Grade	Atezolizumab (N=104)																Best Supportive Care (BSC) (N=101)															
	Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/R ESOLVED		RECOVERED/R WITH SEQUELAE		NOT RECOVERED/N OT RESOLVED		FATAL		RECOVERING/ RESOLVING		UNKNOWN		MISSING			
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Vasculitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Hypophysitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Hypophysitis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Myocarditis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Myocarditis																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Immune-Mediated Severe Cutaneous Reactions																																
All	2	0	0,0	0	0,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Grade 1	2	0	0,0	0	0,0	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Immune-Mediated Severe Cutaneous Reactions																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Autoimmune Hemolytic Anemia																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Autoimmune Hemolytic Anemia																																
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 18APR2022

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_resolved.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ae_resolved_aesi_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 12:11

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Verträglichkeit

Spezifische Verträglichkeit nach SOC/PT

Immunvermittelte Hepatitis nach SOC/PT (deskriptiv)

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	5	4,8	101	100,0	1	1,0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0,0
Hepatobiliary disorders	Hepatic steatosis	n/a	104	100,0	1	1,0	101	100,0	1	1,0
Hepatobiliary disorders	Hyperbilirubin aemia	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations		n/a	104	100,0	11	10,6	101	100,0	4	4,0
Investigations	Alanine aminotransfera se increased	n/a	104	100,0	8	7,7	101	100,0	3	3,0
Investigations	Aspartate aminotransfera se increased	n/a	104	100,0	5	4,8	101	100,0	3	3,0
Investigations	Gamma- glutamyltransf erese increased	n/a	104	100,0	0	0,0	101	100,0	1	1,0
Investigations	Liver function test increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Transaminases increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations	Urine bilirubin increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	5	6,1	71	70,3	1	1,4
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Male	82	78,8	1	1,2	71	70,3	1	1,4
Hepatobiliary disorders	Hepatic steatosis	Female	22	21,2	0	0,0	30	29,7	0	0,0
Hepatobiliary disorders	Hyperbilirubinemia	Male	82	78,8	1	1,2	71	70,3	0	0,0
Hepatobiliary disorders	Hyperbilirubinemia	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations		Male	82	78,8	9	11,0	71	70,3	3	4,2
Investigations		Female	22	21,2	2	9,1	30	29,7	1	3,3
Investigations	Alanine aminotransferase increased	Male	82	78,8	6	7,3	71	70,3	2	2,8

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Alanine aminotransfera se increased	Female	22	21,2	2	9,1	30	29,7	1	3,3
Investigations	Aspartate aminotransfera se increased	Male	82	78,8	4	4,9	71	70,3	2	2,8
Investigations	Aspartate aminotransfera se increased	Female	22	21,2	1	4,5	30	29,7	1	3,3
Investigations	Gamma- glutamyltransf erese increased	Male	82	78,8	0	0,0	71	70,3	1	1,4
Investigations	Gamma- glutamyltransf erese increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Liver function test increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Liver function test increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Transaminases increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Transaminases increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Urine bilirubin increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Urine bilirubin increased	Female	22	21,2	0	0,0	30	29,7	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	4	6,3	62	61,4	1	1,6
Hepatobiliary disorders		\geq 65	40	38,5	1	2,5	39	38,6	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	\geq 65	40	38,5	1	2,5	39	38,6	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	\geq 65	40	38,5	0	0,0	39	38,6	0	0,0
Hepatobiliary disorders	Hepatic steatosis	< 65	64	61,5	1	1,6	62	61,4	1	1,6
Hepatobiliary disorders	Hepatic steatosis	\geq 65	40	38,5	0	0,0	39	38,6	0	0,0
Hepatobiliary disorders	Hyperbilirubi naemia	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Hepatobiliary disorders	Hyperbilirubi naemia	\geq 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigation s		< 65	64	61,5	8	12,5	62	61,4	4	6,5
Investigation s		\geq 65	40	38,5	3	7,5	39	38,6	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Alanine aminotransferase increased	< 65	64	61,5	5	7,8	62	61,4	3	4,8
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	3	7,5	39	38,6	0	0,0
Investigations	Aspartate aminotransferase increased	< 65	64	61,5	3	4,7	62	61,4	3	4,8
Investigations	Aspartate aminotransferase increased	>= 65	40	38,5	2	5,0	39	38,6	0	0,0
Investigations	Gamma- glutamyltransferase increased	< 65	64	61,5	0	0,0	62	61,4	1	1,6
Investigations	Gamma- glutamyltransferase increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Liver function test increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Liver function test increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Transaminases increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Transaminases increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Urine bilirubin increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Urine bilirubin increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xl
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Austral ia	29	27,9	3	10,3	23	22,8	0	0,0
Hepatobiliary disorders		Europe and Middle East	65	62,5	2	3,1	68	67,3	1	1,5
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0,0
Hepatobiliary disorders	Hepatic steatosis	Europe and Middle East	65	62,5	0	0,0	68	67,3	1	1,5
Hepatobiliary disorders	Hepatic steatosis	North America	10	9,6	0	0,0	10	9,9	0	0,0
Hepatobiliary disorders	Hyperbilirubin aemia	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0,0
Hepatobiliary disorders	Hyperbilirubin aemia	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Hepatobiliary disorders	Hyperbilirubin aemia	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations		Asia Pacific and Austral ia	29	27,9	4	13,8	23	22,8	2	8,7
Investigations		Europe and Middle East	65	62,5	6	9,2	68	67,3	2	2,9

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations		North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Alanine aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	2	8,7
Investigations	Alanine aminotransfera se increased	Europe and Middle East	65	62,5	5	7,7	68	67,3	1	1,5
Investigations	Alanine aminotransfera se increased	North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Aspartate aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	1	4,3
Investigations	Aspartate aminotransfera se increased	Europe and Middle East	65	62,5	3	4,6	68	67,3	2	2,9
Investigations	Aspartate aminotransfera se increased	North America	10	9,6	1	10,0	10	9,9	0	0,0
Investigations	Gamma- glutamyltransf erese increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	1	4,3
Investigations	Gamma- glutamyltransf erese increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Gamma- glutamyltransf erese increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Liver function test increased	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0,0
Investigations	Liver function test increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Liver function test increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Transaminases increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0,0
Investigations	Transaminases increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0,0
Investigations	Transaminases increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Urine bilirubin increased	Asia Pacific and Austral ia	29	27,9	1	3,4	23	22,8	0	0,0
Investigations	Urine bilirubin increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Urine bilirubin increased	North America	10	9,6	0	0,0	10	9,9	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 9:26

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Immune-Mediated Hepatitis
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	1	3,0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders		IIIA	46	44,2	5	10,9	53	52,5	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0,0
Hepatobiliary disorders	Hepatic steatosis	IIA	31	29,8	0	0,0	33	32,7	1	3,0
Hepatobiliary disorders	Hepatic steatosis	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Hepatobiliary disorders	Hepatic steatosis	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Hepatobiliary disorders	Hyperbilirubin aemia	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Hepatobiliary disorders	Hyperbilirubin aemia	IIB	27	26,0	0	0,0	15	14,9	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Hyperbilirubin aemia	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Investigations		IIA	31	29,8	3	9,7	33	32,7	4	12,1
Investigations		IIB	27	26,0	2	7,4	15	14,9	0	0,0
Investigations		IIIA	46	44,2	6	13,0	53	52,5	0	0,0
Investigations	Alanine aminotransfera se increased	IIA	31	29,8	3	9,7	33	32,7	3	9,1
Investigations	Alanine aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Alanine aminotransfera se increased	IIIA	46	44,2	5	10,9	53	52,5	0	0,0
Investigations	Aspartate aminotransfera se increased	IIA	31	29,8	2	6,5	33	32,7	3	9,1
Investigations	Aspartate aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Aspartate aminotransfera se increased	IIIA	46	44,2	3	6,5	53	52,5	0	0,0
Investigations	Gamma- glutamyltransf erese increased	IIA	31	29,8	0	0,0	33	32,7	1	3,0
Investigations	Gamma- glutamyltransf erese increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Gamma- glutamyltransf erased increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0
Investigations	Liver function test increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Liver function test increased	IIB	27	26,0	1	3,7	15	14,9	0	0,0
Investigations	Liver function test increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0
Investigations	Transaminases increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Transaminases increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Transaminases increased	IIIA	46	44,2	1	2,2	53	52,5	0	0,0
Investigations	Urine bilirubin increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Urine bilirubin increased	IIB	27	26,0	1	3,7	15	14,9	0	0,0
Investigations	Urine bilirubin increased	IIIA	46	44,2	0	0,0	53	52,5	0	0,0

Includes adverse events occurring on or after the start of treatment in randomization period.

Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	3	2,9	101	100,0	0	0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Hepatic function abnormal	n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations		n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Alanine aminotransfera se increased	n/a	104	100,0	2	1,9	101	100,0	0	0
Investigations	Aspartate aminotransfera se increased	n/a	104	100,0	1	1,0	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:33

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	3	3,7	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	Male	82	78,8	2	2,4	71	70,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	Female	22	21,2	0	0,0	30	29,7	0	0
Investigations		Male	82	78,8	1	1,2	71	70,3	0	0
Investigations		Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Alanine aminotransferase increased	Male	82	78,8	1	1,2	71	70,3	0	0
Investigations	Alanine aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	0	0
Investigations	Aspartate aminotransferase increased	Male	82	78,8	0	0,0	71	70,3	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Aspartate aminotransferase increased	Female	22	21,2	1	4,5	30	29,7	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade \geq 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders		\geq 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	\geq 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Hepatic function abnormal	< 65	64	61,5	2	3,1	62	61,4	0	0
Hepatobiliary disorders	Hepatic function abnormal	\geq 65	40	38,5	0	0,0	39	38,6	0	0
Investigations		< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations		\geq 65	40	38,5	1	2,5	39	38,6	0	0
Investigations	Alanine aminotransfera se increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Alanine aminotransfera se increased	\geq 65	40	38,5	1	2,5	39	38,6	0	0
Investigations	Aspartate aminotransfera se increased	< 65	64	61,5	1	1,6	62	61,4	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Aspartate aminotransfera se increased	>= 65	40	38,5	0	0,0	39	38,6	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sq_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Grade \geq 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	Asia Pacific and Austral ia	29	27,9	2	6,9	23	22,8	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders	Hepatic function abnormal	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Hepatobiliary disorders	Hepatic function abnormal	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations		Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Investigations		North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Alanine aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Investigations	Alanine aminotransfera se increased	Europe and Middle East	65	62,5	2	3,1	68	67,3	0	0
Investigations	Alanine aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0
Investigations	Aspartate aminotransfera se increased	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Aspartate aminotransfera se increased	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Investigations	Aspartate aminotransfera se increased	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Immune-Mediated Hepatitis Grade >= 3
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	3	6,5	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Hepatic function abnormal	IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations		IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations		IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations		IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations	Alanine aminotransfera se increased	IIA	31	29,8	0	0,0	33	32,7	0	0

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Investigations	Alanine aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Alanine aminotransfera se increased	IIIA	46	44,2	2	4,3	53	52,5	0	0
Investigations	Aspartate aminotransfera se increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Aspartate aminotransfera se increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Aspartate aminotransfera se increased	IIIA	46	44,2	1	2,2	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
01MAR2022 9:33

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

All

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Hepatobiliary disorders	Drug-induced liver injury	n/a	104	100,0	1	1,0	101	100,0	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Sex

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	Male	82	78,8	1	1,2	71	70,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	Female	22	21,2	0	0,0	30	29,7	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Age

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders		>= 65	40	38,5	1	2,5	39	38,6	0	0
Hepatobiliary disorders	Drug-induced liver injury	< 65	64	61,5	0	0,0	62	61,4	0	0
Hepatobiliary disorders	Drug-induced liver injury	>= 65	40	38,5	1	2,5	39	38,6	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Region

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders		Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders		North America	10	9,6	0	0,0	10	9,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	Asia Pacific and Austral ia	29	27,9	0	0,0	23	22,8	0	0
Hepatobiliary disorders	Drug-induced liver injury	Europe and Middle East	65	62,5	1	1,5	68	67,3	0	0
Hepatobiliary disorders	Drug-induced liver injury	North America	10	9,6	0	0,0	10	9,9	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
01MAR2022 9:40										

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
 ENDPPOINT: Immune-Mediated Hepatitis Serious
 MODEL: Unstratified analysis
 STUDY: GO29527
 Dichotomous Analysis by Subgroups (Safety)

Subgroup: Tumor stage

			Atezolizumab (N=104)				Best Supportive Care (BSC) (N=101)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Hepatobiliary disorders		IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders		IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders		IIIA	46	44,2	1	2,2	53	52,5	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIA	31	29,8	0	0,0	33	32,7	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIB	27	26,0	0	0,0	15	14,9	0	0
Hepatobiliary disorders	Drug-induced liver injury	IIIA	46	44,2	1	2,2	53	52,5	0	0

Includes adverse events occurring on or after the start of treatment in randomization period.
 Clinical cut-off: 21JAN2021

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_IA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_21JAN2021_29527.xls
 01MAR2022 9:40

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Sonstige Analysen

Nicht im Studienprotokoll vorgesehene antineoplastische Folgetherapien

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: Subsequent Non-Protocol Anti-Cancer Therapy

MODEL: descriptive

STUDY: GO29527

ATC Class Level 2 Other Treatment	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)
Total number of patients with at least one treatment	20 (18.9%)	28 (27.2%)
Total number of treatments	51	73
ANTINEOPLASTIC AGENTS		
Total number of patients with at least one treatment	20 (18.9%)	28 (27.2%)
Total number of treatments	51	73
CARBOPLATIN	11 (10.4%)	10 (9.7%)
PEMBROLIZUMAB	4 (3.8%)	15 (14.6%)
DOCETAXEL	4 (3.8%)	6 (5.8%)
CISPLATIN	4 (3.8%)	5 (4.9%)
GEMCITABINE	5 (4.7%)	4 (3.9%)
PACLITAXEL	4 (3.8%)	3 (2.9%)
PEMETREXED	4 (3.8%)	3 (2.9%)
ATEZOLIZUMAB	0	3 (2.9%)
BEVACIZUMAB	0	3 (2.9%)
ETOPOSIDE	2 (1.9%)	1 (1.0%)
RAMUCIRUMAB	2 (1.9%)	1 (1.0%)
AFATINIB DIMALEATE	1 (0.9%)	1 (1.0%)
DURVALUMAB	1 (0.9%)	1 (1.0%)
GEMCITABINE HYDROCHLORIDE	0	2 (1.9%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (0.9%)	1 (1.0%)
IPILIMUMAB	0	2 (1.9%)
NIVOLUMAB	0	2 (1.9%)
OSIMERTINIB	0	2 (1.9%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	0	2 (1.9%)
VINORELBINE	2 (1.9%)	0
VINORELBINE TARTRATE	1 (0.9%)	1 (1.0%)
CARBOPLATIN;PEMETREXED	1 (0.9%)	0

ATC Class Level 2 Other Treatment	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)
CRIZOTINIB	1 (0.9%)	0
EPACADOSTAT	0	1 (1.0%)
NINTEDANIB	0	1 (1.0%)
SELPERCATINIB	1 (0.9%)	0
CARDIAC THERAPY		
Total number of patients with at least one treatment	4 (3.8%)	3 (2.9%)
Total number of treatments	5	3
PACLITAXEL	4 (3.8%)	3 (2.9%)
OPHTHALMOLOGICALS		
Total number of patients with at least one treatment	0	3 (2.9%)
Total number of treatments	0	4
BEVACIZUMAB	0	3 (2.9%)
INVESTIGATIONAL DRUG		
Total number of patients with at least one treatment	0	1 (1.0%)
Total number of treatments	0	1
EPACADOSTAT	0	1 (1.0%)

Clinical cut-off: 18APR2022

Program: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_cm_fu.sas

Output: root/clinical_studies/R05541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_cm_fu_EGFRALKNOUK_SP263T3_ST23_IT_18APR2022_29527.xls
27JUN2022 15:43

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Sonstige Analysen

Studienabbruch

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: --

MODEL: descriptive

STUDY: GO29527

Patients who Discontinued Study including Reason

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)	All Patients (N=209)
Received Treatment	104 (98.1%)	101 (98.1%)	205 (98.1%)
On-study	84 (79.2%)	65 (63.1%)	149 (71.3%)
Alive: In Follow-Up	84 (79.2%)	65 (63.1%)	149 (71.3%)
Discontinued Study	22 (20.8%)	38 (36.9%)	60 (28.7%)
Death	15 (14.2%)	30 (29.1%)	45 (21.5%)
Lost to Follow-Up	1 (0.9%)	0	1 (0.5%)
Withdrawal by Subject	6 (5.7%)	7 (6.8%)	13 (6.2%)
Physician Decision	0	1 (1.0%)	1 (0.5%)

Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ds_study.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ds_study_EGFRALKNOUK_SP263T3_ST23_IT_18APR2022_29527.xls
14JUN2022 13:38

Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Sonstige Analysen

Behandlungsabbruch

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations

ENDPOINT: --

MODEL: descriptive

STUDY: GO29527

Patients who Discontinued Treatment including Reason

	Atezolizumab (N=104)	Best Supportive Care(BSC) (N=101)	All Patients (N=205)
Atezo/BSC Treatment Status			
Completed	77 (74.0%)	74 (73.3%)	151 (73.7%)
Discontinued	27 (26.0%)	27 (26.7%)	54 (26.3%)
Atezo/BSC Treatment Discontinuation Reason			
Adverse Event	20 (19.2%)	1 (1.0%)	21 (10.2%)
Protocol Deviation	0	1 (1.0%)	1 (0.5%)
Withdrawal by Subject	5 (4.8%)	2 (2.0%)	7 (3.4%)
Disease Relapse	2 (1.9%)	23 (22.8%)	25 (12.2%)

Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ds_trt.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_ds_trt_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
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Vollständige Darstellung relevanter Ergebnisse

Endpunkte der Studie IMpower010

Zweiter Datenschnitt 18.04.2022

Sonstige Analysen

Dauer des Survival Follow-up

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Efficacy Follow-up [Months]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care (BSC) (N=103)
n	106	103
Mean (SD)	47.29 (13.20)	41.79 (17.01)
Median	49,53	46,13
25% and 75%-ile	43.20 - 54.97	29.77 - 53.68
Min - Max	0.1 - 69.4	0.2 - 72.8

Only randomization period was considered.

Efficacy Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date) - Randomization Date.
Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_fu_FUEFF_EGFRALKNOUK_SP263T3_ST23_IT_18APR2022_29527.xls
14JUN2022 15:10

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-III A Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Safety Follow-up at 30 Days [Months]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=104)	Best Supportive Care (BSC) (N=101)
n	104	101
Mean (SD)	9.85 (3.58)	10.79 (3.26)
Median	11,33	12,02
25% and 75%-ile	11.09 - 11.65	10.91 - 12.25
Min - Max	1.0 - 17.0	1.0 - 24.9

Only randomization period was considered.

Safety Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date, Date of Last Dose of Study Treatment + 30 Days (Date of Last Study Assessment for Patients in Arm BSC), Initiation of Subsequent Anti-Cancer Therapy) - Treatment Start Date
Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_fu_AER30_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 15:44

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIa Patients, SP263 TC \geq 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Safety Follow-up at 90 Days [Months]
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=104)	Best Supportive Care (BSC) (N=101)
n	104	101
Mean (SD)	11.78 (3.65)	12.51 (3.61)
Median	13,31	13,96
25% and 75%-ile	12.96 - 13.62	12.88 - 14.19
Min - Max	2.1 - 18.9	1.6 - 26.9

Only randomization period was considered.

Safety Follow-Up Duration was calculated as min(Datacut Date, Death Date, Lost to Follow Up Date, Withdrawal of Consent Date, Study Discontinuation Date, Date of Last Dose of Study Treatment + 90 Days (Date of Last Study Assessment for Patients in Arm BSC), Initiation of Subsequent Anti-Cancer Therapy) - Treatment Start Date
Clinical cut-off: 18APR2022

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_fu.sas

Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_OS_IA/prod/output/t_fu_AER90_EGFRALKNOUK_SP263T3_ST23_SE_18APR2022_29527.xls
27JUN2022 15:45