Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Atezolizumab (Tecentriq®)

Roche Pharma AG

Modul 4A
Anhang 4-G2

Erwachsene Patienten mit NSCLC nach vollständiger Resektion und platinbasierter Chemotherapie mit hohem Risiko für ein Rezidiv und deren Tumoren eine PD-L1-Expression auf ≥ 50 % der Tumorzellen aufweisen und kein EGFR-mutiertes oder ALK-positives NSCLC haben.

Vollständige Darstellung der für das vorliegende Dossier relevanten Ergebnisse in unveränderter Form
Aktueller Datenschnitt 26.01.2024

Stand: 26.09.2024

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Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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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: Overall Survival
MODEL: Strstified 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	22	20,8	84	79,2	NE	54,6	NE	NE	NE	NE	103	100,0	41	39,8	62	60,2	38,9	27,8	56,1	87,1	72,0	NE	0,0046	0,47	0,28	0,80		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_str_OS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_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: Overall Survival
MODEL: Stratified Analysis by Sex, Histology, Tumor Stage
STUDY: GO29527
Time to Event Landmark Analysis (Efficacy)

	Atezolizumab (N=106)		Best Supportive Care(BSC) (N=103)
Patients with event (%)	22 (20.8%)		41 (39.8%)
Earliest contributing event			
Death	22		41
Patients without event (%)	84 (79.2%)		62 (60.2%)
Time to event (months)			
Median	NE		87,1
95% CI	NE		(72.0, NE)
25% and 75%-itle	NE		38.9 - NE
Range	0.2* - 90.6*		0.2* - 91.9*
Stratified Analysis			
p-value (log-rank)		0,0046	
Hazard Ratio		0,474	
95% CI		(0.280, 0.803)	
Unstratified Analysis			
p-value (log-rank)		0,0016	
Hazard Ratio		0,443	
95% CI		(0.264, 0.745)	
Time Point Analysis			
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			

	Atezolizumab (N=106)		Best Supportive Care(BSC) (N=103)
Patients with event (%)	22 (20.8%)		41 (39.8%)
Patients remaining at risk	78		58
Event Free Rate (%)	82,13		63,72
95% CI	(74.65, 89.62)		(54.09, 73.34)
Difference in Event Free Rate		18,42	
95% CI		(6.23, 30.61)	
p-value (Z-test)		0,0031	
7 Years			
Patients remaining at risk	6		4
Event Free Rate (%)	76,09		50,87
95% CI	(66.86, 85.31)		(35.79, 65.96)
Difference in Event Free Rate		25,21	
95% CI		(7.53, 42.89)	
p-value (Z-test)		0,0052	

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: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_ef_tte_357.sas
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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)												log-rank	Atezolizumab vs. Best Supportive Care(BSC)				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							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	34	32,1	72	67,9	36,0	27,9	68,5	NE	NE	NE	103	100,0	55	53,4	48	46,6	11,1	7,3	21,4	42,9	32,0	NE	0,0026	0,52	0,33	0,80		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_str_DFS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_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)												log-rank	Atezolizumab vs. Best Supportive Care(BSC)				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							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	28	26,4	78	73,6	40,6	30,1	NE	NE	NE	NE	103	100,0	47	45,6	56	54,4	11,1	7,3	23,9	NE	34,2	NE	0,0035	0,49	0,30	0,80		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_str_RECUR_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_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	%	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	6	5,7	100	94,3	NE	NE	NE	NE	NE	NE	103	100,0	8	7,8	95	92,2	87,1	67,0	NE	87,1	NE	NE	0,3926	0,63	0,22	1,83		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
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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=101)												Best Supportive Care(BSC) (N=96)												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	101	100,0	34	33,7	67	66,3	30,1	23,8	63,4	NE	68,5	NE	96	100,0	51	53,1	45	46,9	17,7	8,1	26,0	48,2	30,2	NE	0,0130	0,57	0,36	0,89		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_str_DFSO_BICR_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
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Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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	22	20,8	84	79,2	NE	54,6	NE	NE	NE	NE	103	100,0	41	39,8	62	60,2	38,9	27,8	56,1	87,1	72,0	NE	0,0016	0,44	0,26	0,74	Convergence criterion (GCONV=1E-8) satisfied.	
Sex per eCRF	Male	84	79,2	17	20,2	67	79,8	NE	54,6	NE	NE	NE	NE	73	70,9	26	35,6	47	64,4	33,4	26,1	67,0	NE	72,6	NE	0,0142	0,47	0,26	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,7039
	Female	22	20,8	5	22,7	17	77,3	NE	25,7	NE	NE	NE	NE	30	29,1	15	50,0	15	50,0	41,1	24,6	72,0	79,7	43,5	NE	0,0463	0,37	0,13	1,02	Convergence criterion (GCONV=1E-8) satisfied.	
Age at Randomization	< 65	65	61,3	11	16,9	54	83,1	NE	63,4	NE	NE	NE	NE	62	60,2	23	40,3	37	59,7	38,9	26,0	72,0	87,1	72,0	NE	0,0053	0,38	0,19	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,4691
	>= 65	41	38,7	11	26,8	30	73,2	61,1	36,7	NE	NE	NE	NE	41	39,8	16	39,0	25	61,0	39,2	26,2	67,0	NE	52,6	NE	0,1367	0,66	0,28	1,21	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic Region	Asia Pacific and Australia	30	28,3	3	10,0	27	90,0	NE	68,5	NE	NE	NE	NE	24	23,3	7	29,2	17	70,8	56,1	39,2	NE	NE	67,0	NE	0,0443	0,27	0,07	1,06	Convergence criterion (GCONV=1E-8) satisfied.	0,5740
	Europe and Middle East	66	62,3	17	25,8	49	74,2	63,4	36,7	NE	NE	NE	NE	68	66,0	28	41,2	40	58,8	27,8	22,5	56,0	79,7	63,9	NE	0,0389	0,54	0,29	0,98	Convergence criterion (GCONV=1E-8) satisfied.	
	North America	10	9,4	2	20,0	8	80,0	NE	38,5	NE	NE	NE	NE	11	10,7	6	54,5	5	45,5	43,5	36,4	NE	72,6	43,5	NE	0,0826	0,27	0,05	1,32	Convergence criterion (GCONV=1E-8) satisfied.	
Race/Ethnicity	White	71	67,0	17	23,9	54	76,1	73,9	46,9	NE	NE	NE	NE	77	74,8	32	41,6	45	58,4	33,4	24,6	56,6	79,7	72,0	NE	0,0151	0,49	0,27	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,3200
	Asian	31	29,2	3	9,7	28	90,3	NE	NE	NE	NE	NE	NE	24	23,3	8	33,3	16	66,7	50,7	36,4	NE	NE	56,1	NE	0,0183	0,23	0,05	0,87	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	
	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.	
Tumor stage per eCRF	IIA	31	29,2	7	22,6	24	77,4	NE	46,6	NE	NE	NE	NE	33	32,0	12	36,4	21	63,6	52,6	28,6	NE	NE	67,0	NE	0,1894	0,54	0,21	1,37	Convergence criterion (GCONV=1E-8) satisfied.	0,2226
	IIB	27	25,5	7	25,9	20	74,1	63,4	33,4	NE	NE	NE	NE	13	14,6	4	26,7	11	73,3	79,7	30,8	NE	NE	79,7	NE	0,9652	0,97	0,28	3,33	Convergence criterion (GCONV=1E-8) satisfied.	
	IIIA	48	45,3	8	16,7	40	83,3	NE	68,5	NE	NE	NE	NE	55	53,4	25	45,5	30	54,5	29,8	22,5	47,9	87,1	47,9	NE	0,0017	0,30	0,14	0,67	Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy Regimen before Randomization	Cisplatin/Vinorelbine	44	41,5	10	22,7	34	77,3	68,5	46,6	NE	NE	NE	NE	36	35,0	16	44,4	20	55,6	39,2	30,8	72,0	79,7	63,9	NE	0,0546	0,47	0,21	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,4437
	Cisplatin/Docetaxel	13	12,3	1	7,7	12	92,3	NE	NE	NE	NE	NE	NE	19	18,4	8	42,1	11	57,9	26,1	13,5	NE	NE	26,2	NE	0,0336	0,14	0,02	1,15	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Gemcitabine	20	18,9	5	25,0	15	75,0	73,9	36,7	NE	NE	73,9	NE	16	15,5	5	31,3	11	68,8	43,5	18,8	NE	NE	43,5	NE	0,3685	0,57	0,18	1,88	Convergence criterion (GCONV=1E-8) satisfied.	
	Cisplatin/Pemetrexed	29	27,4	6	20,7	23	79,3	NE	33,4	NE	NE	NE	NE	32	31,1	12	37,5	20	62,5	41,1	22,2	NE	87,1	50,7	NE	0,1988	0,53	0,20	1,42	Convergence criterion (GCONV=1E-8) satisfied.	
Histology per eCRF	Squamous	47	44,3	12	25,5	35	74,5	73,9	38,5	NE	NE	NE	NE	45	43,7	15	33,3	30	66,7	56,1	26,1	NE	79,7	67,0	NE	0,2325	0,63	0,30	1,35	Convergence criterion (GCONV=1E-8) satisfied.	0,1919
	Non-Squamous	59	55,7	10	16,9	49	83,1	NE	54,6	NE	NE	NE	NE	58	56,3	26	44,8	32	55,2	36,4	22,2	50,7	87,1	48,2	NE	0,0016	0,33	0,16	0,68	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	4	44,4	5	55,6	34,5	22,5	NE	NE	27,8	NE	0,1845	0,33	0,06	1,83	Convergence criterion (GCONV=1E-8) satisfied.	0,3750
	Previous	79	74,5	14	17,7	65	82,3	NE	68,5	NE	NE	NE	NE	73	70,9	28	38,4	45	61,6	39,2	26,1	67,0	87,1	72,6	NE	0,0032	0,39	0,21	0,75	Convergence criterion (GCONV=1E-8) satisfied.	
	Current	16	15,1	6	37,5	10	62,5	36,7	25,7	NE	NE	50,2	NE	21	20,4	9	42,9	12	57,1	38,9	23,6	72,0	72,0	38,9	NE	0,7288	0,83	0,30	2,34	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG Status	0	66	62,3	14	21,2	52	78,8	73,9	61,1	NE	NE	NE	NE	53	51,5	19	35,8	34	64,2	41,1	29,8	72,0	NE	67,0	NE	0,0363	0,48	0,24	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,7112
	1 and 2 combined	40	37,7	8	20,0	32	80,0	NE	36,7	NE	NE	NE	NE	50	48,5	22	44,0	28	56,0	33,7	22,5	50,7	79,7	48,2	NE	0,0264	0,61	0,18	0,92	Convergence criterion (GCONV=1E-8) satisfied.	
Regional Lymph Node Stage (pN)	N0	30	28,3	6	20,0	24	80,0	NE	33,4	NE	NE	NE	NE	20	19,4	7	35,0	13	65,0	49,8	36,4	NE	79,7	56,1	NE	0,3283	0,58	0,20	1,74	Convergence criterion (GCONV=1E-8) satisfied.	0,5004
	N1	39	36,8	9	23,1	30	76,9	NE	46,9	NE	NE	NE	NE	43	41,7	14	32,6	29	67,4	52,6	28,6	NE	NE	72,6	NE	0,2058	0,59	0,23	1,35	Convergence criterion (GCONV=1E-8) satisfied.	
	N2	37	34,9	7	18,9	30	81,1	73,9	33,4	NE	NE	NE	NE	40	38,8	20	50,0	20	50,0	26,2	22,2	48,2	72,0	36,4	NE	0,0096	0,31	0,13	0,75	Convergence criterion (GCONV=1E-8) satisfied.	
Time from Surgery to 1st Chemotherapy (days)	<= 60	68	64,2	13	19,1	55	80,9	NE	54,6	NE	NE	NE	NE	68	66,0	28	41,2	40	58,8	29,8	22,5	63,9	79,7	72,6	NE	0,0048	0,49	0,21	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,5819
	> 60	38	35,8	9	23,7	29	76,3	73,9	36,7	NE	NE	NE	NE	35	34,0	13	37,1	22	62,9	41,1	30,8	72,0	NE	56,1	NE	0,1232	0,52	0,22	1,21	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_sg_OS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
24APR2024 8:00

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	34	32,1	72	67,9	36,0	27,8	68,5	NE	NE	NE	103	100,0	55	53,4	48	46,6	11,1	7,3	21,4	42,9	32,0	NE	0,0009	0,49	0,32	0,75	Convergence criterion (GCONV=1E-8) satisfied.		
Sex per eCRF	Male	84	79,2	26	31,0	58	69,0	36,0	27,8	NE	NE	NE	NE	73	70,9	33	45,2	40	54,8	12,0	7,3	34,2	NE	35,3	NE	0,0368	0,58	0,35	0,97	Convergence criterion (GCONV=1E-8) satisfied.		0,3382
	Female	22	20,8	8	36,4	14	63,6	36,6	4,7	NE	NE	41,8	NE	30	29,1	22	73,3	8	26,7	9,0	4,5	17,8	31,0	10,2	43,5	0,0133	0,37	0,16	0,84	Convergence criterion (GCONV=1E-8) satisfied.		
Age at Randomization	< 65	65	61,3	19	29,2	46	70,8	36,0	27,8	NE	NE	NE	NE	62	60,2	32	51,6	30	48,4	12,2	8,0	33,4	41,1	33,4	NE	0,0081	0,47	0,27	0,83	Convergence criterion (GCONV=1E-8) satisfied.		0,8573
	>= 65	41	38,7	15	36,6	26	63,4	36,7	22,2	68,5	NE	44,6	NE	41	39,8	23	56,1	18	43,9	7,3	4,2	19,4	42,9	17,2	NE	0,0451	0,62	0,27	1,00	Convergence criterion (GCONV=1E-8) satisfied.		
Geographic Region	Asia Pacific and Australia	30	28,3	7	23,3	23	76,7	68,5	14,7	NE	NE	68,5	NE	24	23,3	11	45,8	13	54,2	9,0	4,2	67,0	67,0	11,1	NE	0,0728	0,43	0,17	1,11	Convergence criterion (GCONV=1E-8) satisfied.		0,9065
	Europe and Middle East	66	62,3	23	34,8	43	65,2	36,1	30,1	55,9	NE	55,9	NE	68	66,0	37	54,4	31	45,6	12,0	4,5	30,1	41,1	32,0	NE	0,0085	0,51	0,30	0,86	Convergence criterion (GCONV=1E-8) satisfied.		
	North America	10	9,4	4	40,0	6	60,0	11,8	2,3	NE	NE	11,8	NE	11	10,7	7	63,6	4	36,4	17,2	7,3	43,5	39,6	17,2	NE	0,3726	0,58	0,17	1,97	Convergence criterion (GCONV=1E-8) satisfied.		
Race/Ethnicity	White	71	67,0	24	33,8	47	66,2	36,1	27,9	NE	NE	NE	NE	77	74,8	42	54,5	35	45,5	12,2	8,0	30,1	41,7	33,4	NE	0,0054	0,50	0,30	0,82	Convergence criterion (GCONV=1E-8) satisfied.		0,8972
	Asian	31	29,2	8	25,8	23	74,2	36,0	12,0	NE	NE	68,5	NE	24	23,3	11	45,8	13	54,2	9,0	4,2	67,0	67,0	11,1	NE	0,1080	0,48	0,19	1,20	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		
	Unknown	2	1,9	1	50,0	1	50,0	11,2	11,2	NE	NE	11,2	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.		
Tumor stage per eCRF	IIA	31	29,2	7	22,6	24	77,4	NE	36,7	NE	NE	NE	NE	33	32,0	16	48,5	17	51,5	29,0	10,0	42,9	67,0	30,1	NE	0,0264	0,38	0,16	0,92	Convergence criterion (GCONV=1E-8) satisfied.		0,1585
	IIB	27	25,5	12	44,4	15	55,6	32,3	24,0	36,6	51,8	35,3	NE	15	14,6	6	40,0	9	60,0	10,2	4,0	NE	NE	32,0	NE	0,7930	1,14	0,43	3,04	Convergence criterion (GCONV=1E-8) satisfied.		
	IIIA	48	45,3	15	31,3	33	68,8	29,9	12,0	NE	NE	68,5	NE	55	53,4	33	60,0	22	40,0	8,0	4,5	17,2	34,2	17,2	NE	0,0030	0,41	0,22	0,75	Convergence criterion (GCONV=1E-8) satisfied.		
Chemotherapy Regimen before Randomization	Cisplatin/Vinorelbine	44	41,5	12	27,3	32	72,7	44,5	33,4	NE	NE	NE	NE	36	35,0	20	55,6	16	44,4	14,3	4,0	32,0	44,5	29,7	NE	0,0105	0,40	0,20	0,83	Convergence criterion (GCONV=1E-8) satisfied.		0,6335
	Cisplatin/Docetaxel	13	12,3	3	23,1	10	76,9	35,3	18,1	NE	NE	35,3	NE	19	18,4	9	47,4	10	52,6	4,5	3,8	45,6	NE	8,0	NE	0,1770	0,42	0,11	1,54	Convergence criterion (GCONV=1E-8) satisfied.		
	Cisplatin/Gemcitabine	20	18,9	8	40,0	12	60,0	32,3	24,0	NE	NE	36,1	NE	16	15,5	6	37,5	10	62,5	35,3	8,0	NE	NE	35,3	NE	0,8243	0,87	0,30	2,52	Convergence criterion (GCONV=1E-8) satisfied.		
	Cisplatin/Pemetrexed	29	27,4	11	37,9	18	62,1	22,2	11,8	NE	NE	29,8	NE	32	31,1	20	62,5	12	37,5	10,2	4,7	21,4	35,7	13,3	NE	0,0534	0,49	0,24	1,03	Convergence criterion (GCONV=1E-8) satisfied.		
Histology per eCRF	Squamous	47	44,3	15	31,9	32	68,1	36,1	25,1	NE	NE	68,5	NE	45	43,7	19	42,2	26	57,8	12,0	7,3	35,3	NE	33,4	NE	0,2436	0,67	0,34	1,32	Convergence criterion (GCONV=1E-8) satisfied.		0,2469
	Non-Squamous	59	55,7	19	32,2	40	67,8	36,0	22,2	NE	NE	NE	NE	58	56,3	36	62,1	22	37,9	9,6	4,2	19,4	36,8	17,8	NE	0,0009	0,40	0,23	0,70	Convergence criterion (GCONV=1E-8) satisfied.		
Smoking History	Never	11	10,4	6	54,5	5	45,5	29,9	3,9	36,6	35,3	29,9	NE	9	8,7	6	66,7	3	33,3	12,1	9,0	37,3	25,3	12,0	NE	0,8018	0,86	0,28	2,70	Convergence criterion (GCONV=1E-8) satisfied.		0,5173
	Previous	79	74,5	22	27,8	57	72,2	41,8	24,3	NE	NE	NE	NE	73	70,9	38	52,1	35	47,9	8,0	4,3	17,8	43,5	29,0	NE	0,0011	0,43	0,25	0,72	Convergence criterion (GCONV=1E-8) satisfied.		
	Current	16	15,1	6	37,5	10	62,5	30,1	25,1	NE	NE	30,1	NE	21	20,4	11	52,4	10	47,6	34,2	16,5	45,6	45,6	34,2	NE	0,4786	0,70	0,26	1,89	Convergence criterion (GCONV=1E-8) satisfied.		
ECOG Status	0	66	62,3	22	33,3	44	66,7	35,3	24,3	NE	NE	NE	NE	53	51,5	26	49,1	27	50,9	10,2	4,5	29,0	67,0	23,9	NE	0,0311	0,54	0,31	0,95	Convergence criterion (GCONV=1E-8) satisfied.		0,7578
	1 and 2 combined	40	37,7	12	30,0	28	70,0	36,0	24,0	NE	NE	36,7	NE	50	48,5	29	58,0	21	42,0	12,1	7,3	32,0	41,7	30,1	NE	0,0215	0,66	0,23	0,91	Convergence criterion (GCONV=1E-8) satisfied.		
Regional Lymph Node Stage (pN)	N0	30	28,3	11	36,7	19	63,3	35,3	30,1	NE	NE	36,1	NE	20	19,4	9	45,0	11	55,0	21,1	4,0	NE	NE	32,0	NE	0,6897	0,84	0,35	2,02	Convergence criterion (GCONV=1E-8) satisfied.		0,4284
	N1	39	36,8	10	25,6	29	74,4	68,5	36,6	NE	NE	NE	NE	43	41,7	20	46,5	23	53,5	29,0	4,3	41,1	67,0	35,7	NE	0,0395	0,46	0,21	0,98	Convergence criterion (GCONV=1E-8) satisfied.		
	N2	37	34,9	13	35,1	24	64,9	22,2	12,0	NE	NE	32,3	NE	40	38,8	26	65,0	14	35,0	8,0	4,7	13,3	19,4	11,1	45,6	0,0057	0,40	0,21	0,78	Convergence criterion (GCONV=1E-8) satisfied.		
Time from Surgery to 1st Chemotherapy (days)	<= 60	68	64,2	18	26,5	50	73,5	44,5	30,1	NE	NE	NE	NE	68	66,0	36	52,9	32	47,1	12,0	7,3	29,7	43,5	30,1	NE	0,0011	0,49	0,23	0,71	Convergence criterion (GCONV=1E-8) satisfied.		0,3033
	> 60	38	35,8	16	42,1	22	57,9	24,3	11,8	41,8	NE	36,7	NE	35	34,0	19	54,3	16	45,7	10,0	4,3	34,2	36,4	17,2	NE	0,1841	0,64	0,33	1,24	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_tte_sg_DFS_EGFRALKNOUK_SP263?3_ST23_IT_26JAN2024_29527.xls
24APR2024 8:04

Endpunkte der Studie IMpower010

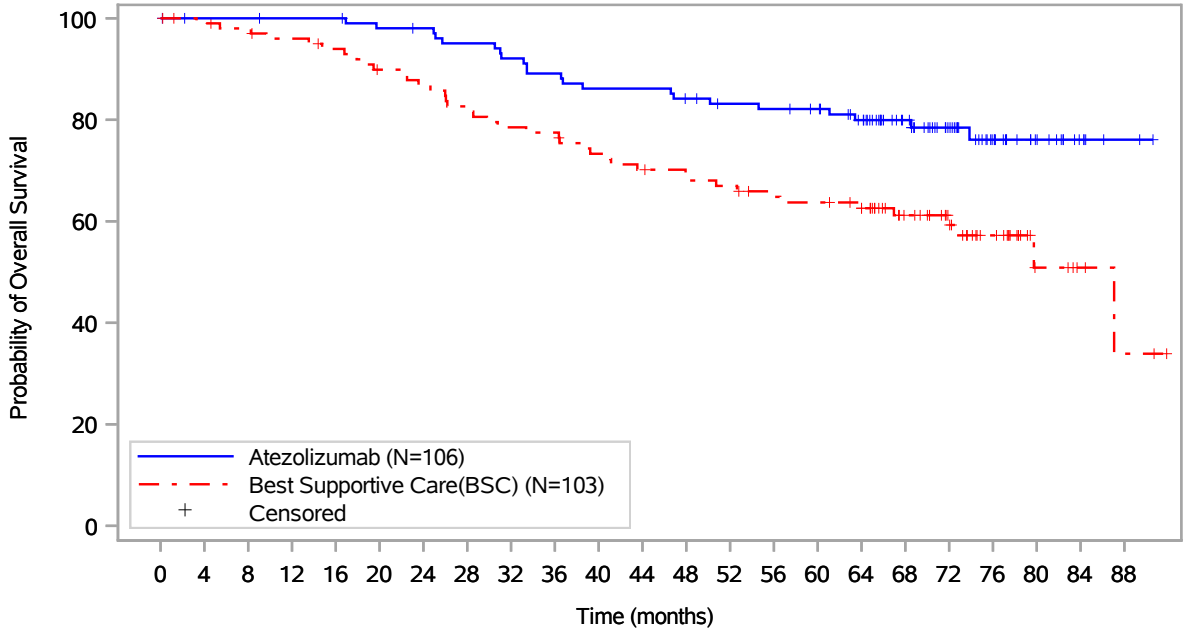
Aktueller Datenschnitt vom 26.01.2024

Wirksamkeit

KM Plots

Stratifiziert

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIA Patients, SP263 TC >= 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	96	93	90	87	87	84	81	80	78	71	55	40	25	14	6	2
Best Supportive Care(BSC) (N=103)	103	100	98	95	92	87	84	79	76	75	70	67	65	63	60	58	55	41	31	21	7	4	2
Patients censored																							
Atezolizumab (N=106)	0	2	2	3	3	4	5	5	5	5	5	5	6	8	8	10	15	31	45	59	70	78	82
Best Supportive Care(BSC) (N=103)	0	2	3	4	5	6	6	6	6	6	7	7	8	8	10	10	14	25	34	43	56	59	60

Clinical cut-off: 26JAN2024

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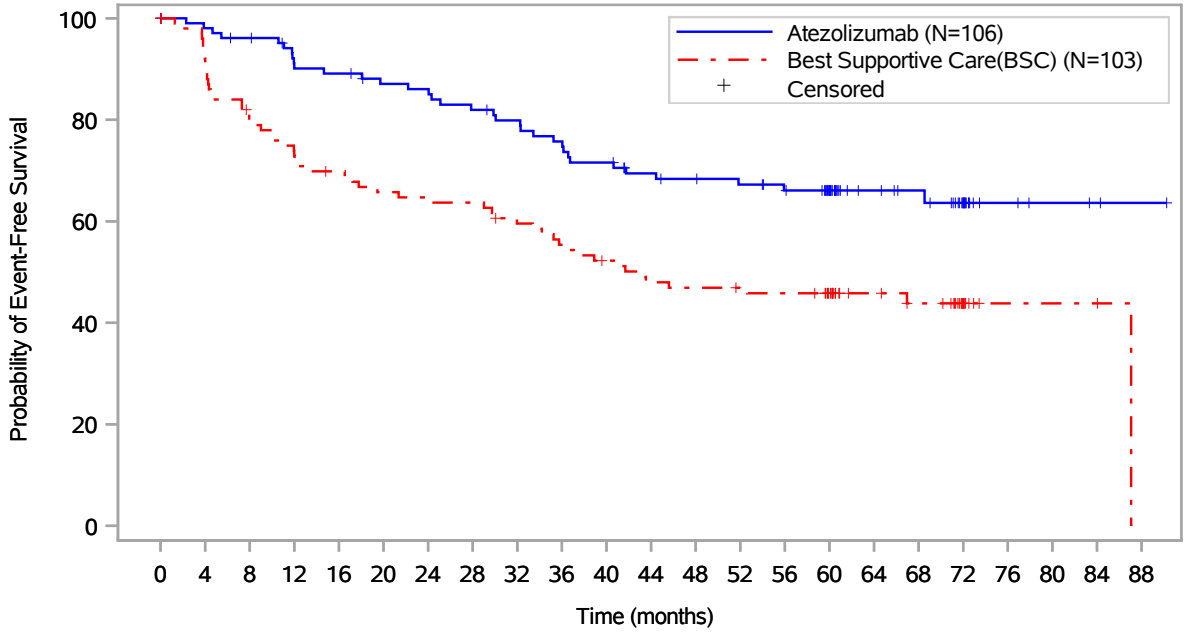
Output: ..ysis/ACE_DFS_FA/prod/output/g_km_OS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.pdf
24APR2024 15:21

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
STUDY: GO29527

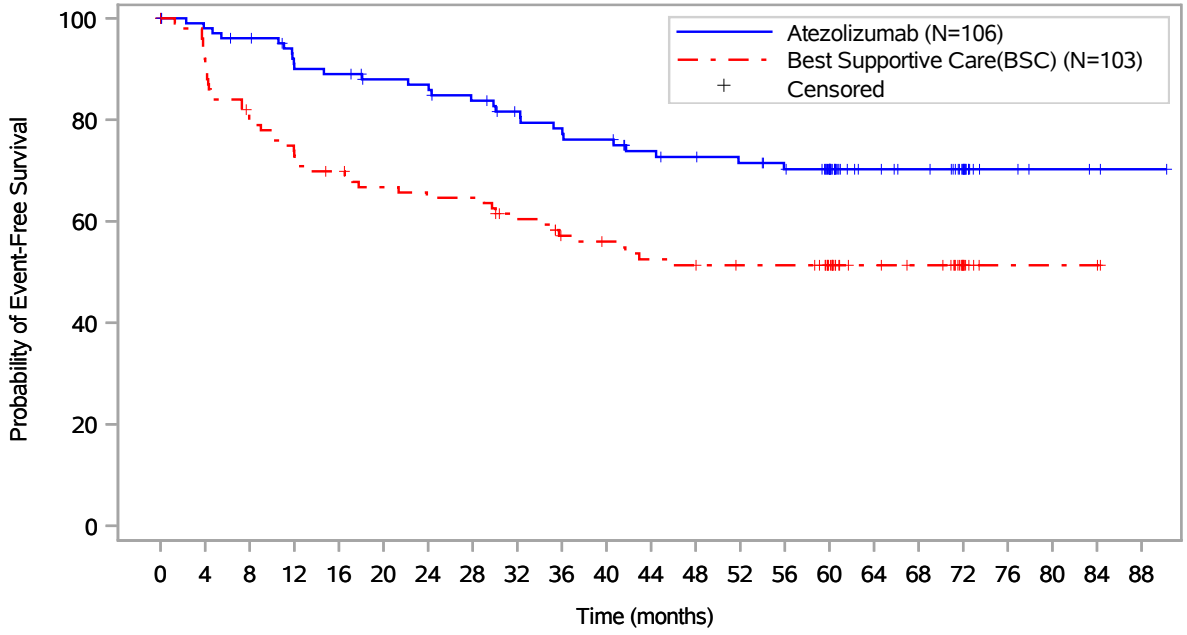


Patients at risk																						
Atezolizumab (N=106)	106	101	98	90	89	85	84	80	77	73	69	64	62	60	57	48	30	27	18	5	3	2	1
Best Supportive Care(BSC) (N=103)	103	92	78	72	68	64	62	62	57	53	49	45	44	43	42	35	24	21	9	2	2	2	NE
Patients censored																							
Atezolizumab (N=106)	0	3	4	6	6	8	8	8	9	9	9	12	13	14	16	25	43	46	54	67	69	70	71
Best Supportive Care(BSC) (N=103)	0	3	4	4	5	5	5	5	6	6	7	7	7	8	8	15	26	28	40	47	47	47	NE

Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..sis/ACE_DFS_FA/prod/output/g_km_DFS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.pdf
24APR2024 15:24

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
STUDY: GO29527

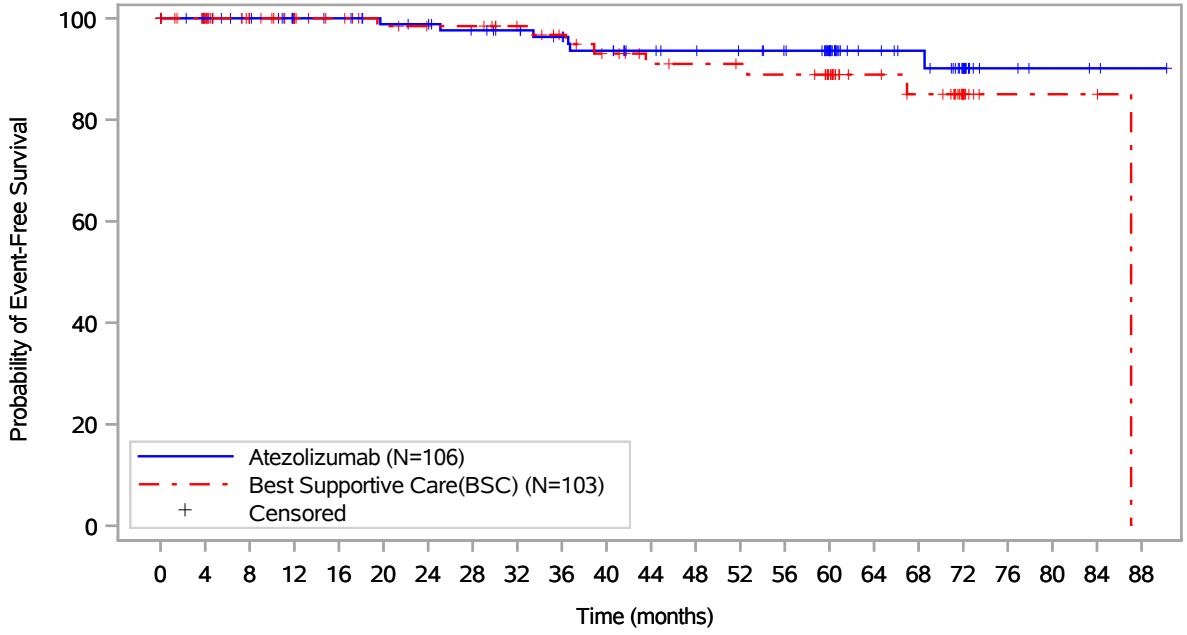


Patients at risk																						
Atezolizumab (N=106)	106	100	97	89	88	84	83	79	74	71	69	64	62	60	57	48	29	26	18	5	3	2	1
Best Supportive Care(BSC) (N=103)	103	92	78	72	68	64	62	62	56	50	48	45	44	42	42	34	23	21	9	2	2	2	NE
Patients censored																							
Atezolizumab (N=106)	0	4	5	7	7	10	10	11	14	14	14	17	18	19	21	30	49	52	60	73	75	76	77
Best Supportive Care(BSC) (N=103)	0	3	4	4	5	6	6	6	8	11	12	12	12	14	14	22	33	35	47	54	54	54	NE

Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..s/ACE_DFS_FA/prod/output/g_km_RECUR_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.pdf
24APR2024 15:27

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
STUDY: GO29527

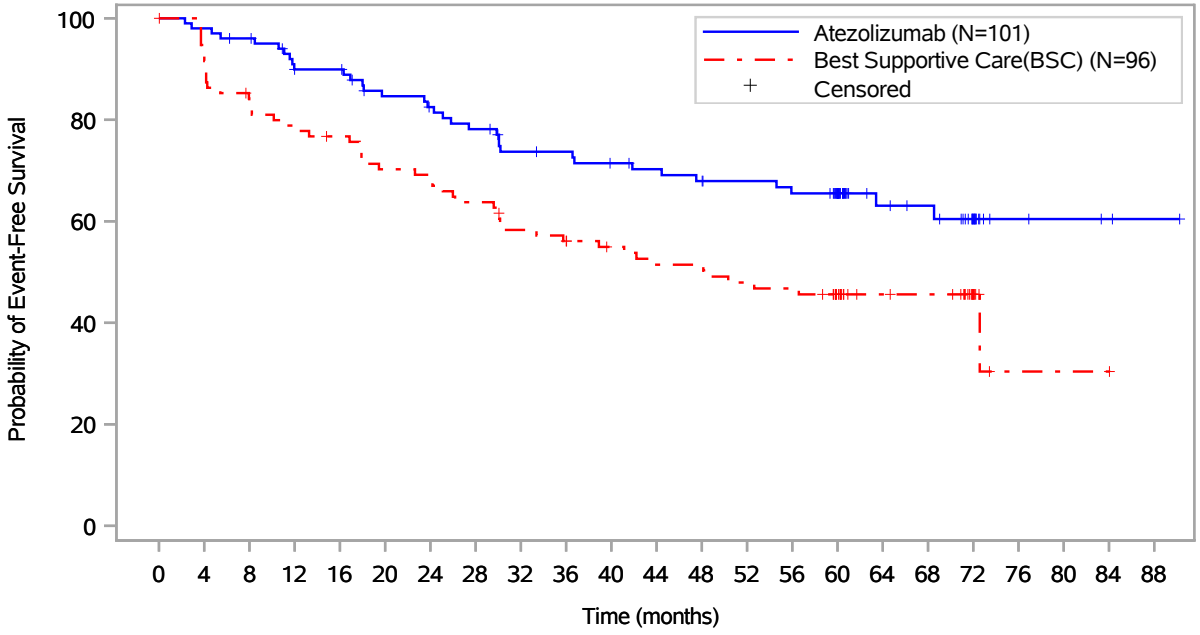


Patients at risk																						
Atezolizumab (N=106)	106	101	98	90	89	85	84	80	77	73	69	64	62	60	57	48	30	27	18	5	3	2	1
Best Supportive Care(BSC) (N=103)	103	92	78	72	68	64	62	62	57	53	49	45	44	43	42	35	24	21	9	2	2	2	NE
Patients censored																							
Atezolizumab (N=106)	0	5	8	16	17	20	21	24	27	30	32	37	39	41	44	53	71	74	82	95	97	98	99
Best Supportive Care(BSC) (N=103)	0	11	25	31	35	38	40	40	45	48	50	53	54	55	55	62	73	75	87	94	94	94	NE

Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_DTHNOREC_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.pdf
24APR2024 15:32

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
STUDY: GO29527



Patients at risk																						
Atezolizumab (N=101)	101	99	96	87	87	79	76	72	66	65	62	60	58	56	54	46	26	24	15	4	3	2	1
Best Supportive Care(BSC) (N=96)	96	89	78	73	71	65	63	59	53	51	47	44	44	41	40	31	21	20	8	1	1	1	NE
Patients censored																							
Atezolizumab (N=101)	0	0	1	4	4	7	8	8	10	11	12	13	13	15	15	23	42	44	52	63	64	65	66
Best Supportive Care(BSC) (N=96)	0	1	2	2	3	3	3	3	4	4	7	7	7	7	7	15	25	26	38	44	44	44	NE

Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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24APR2024 15:43

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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	34	32,1	103	100,0	55	53,4	0,43		Algorithm converged.	0,24	0,77	-0,191		Algorithm converged.	-0,323	-0,059	0,61		Algorithm converged.	0,44	0,84	0,0023	1,65		Algorithm converged.	1,20	2,27

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_eff_resp_adj_DFS_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
24APR2024 7:40

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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.	
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 19:58

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 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					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	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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:01

Vollständige Darstellung 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					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	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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:04

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 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					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	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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:07

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 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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:11

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 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
	>= 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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:14

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 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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTWDAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:16

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

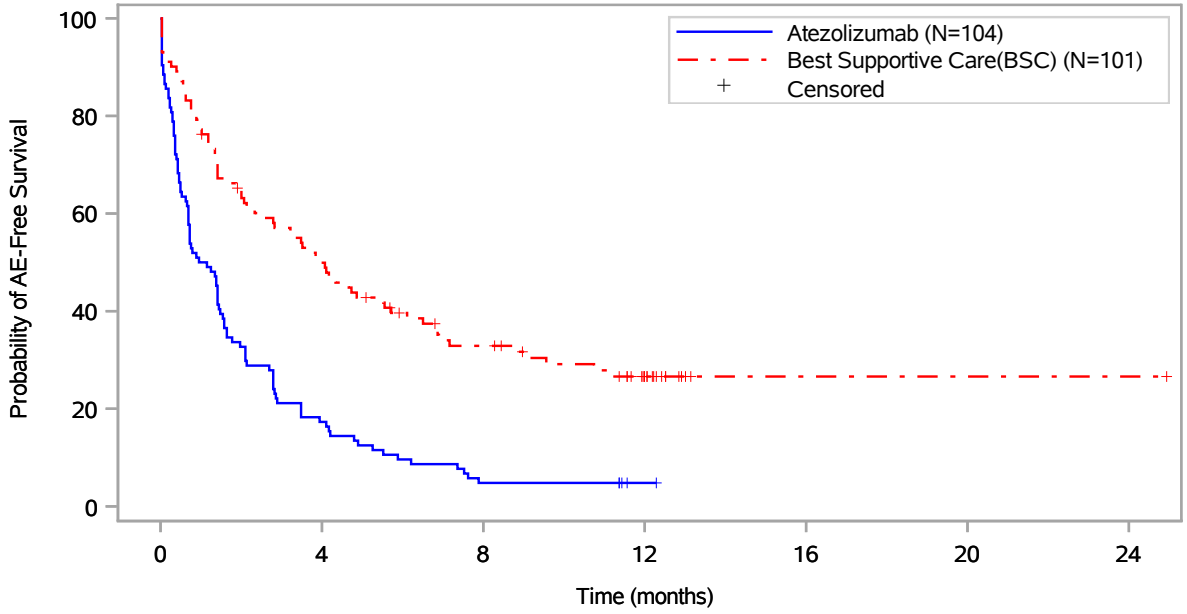
Verträglichkeit

Generelle Verträglichkeit

KM Plots

Unstratifiziert

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

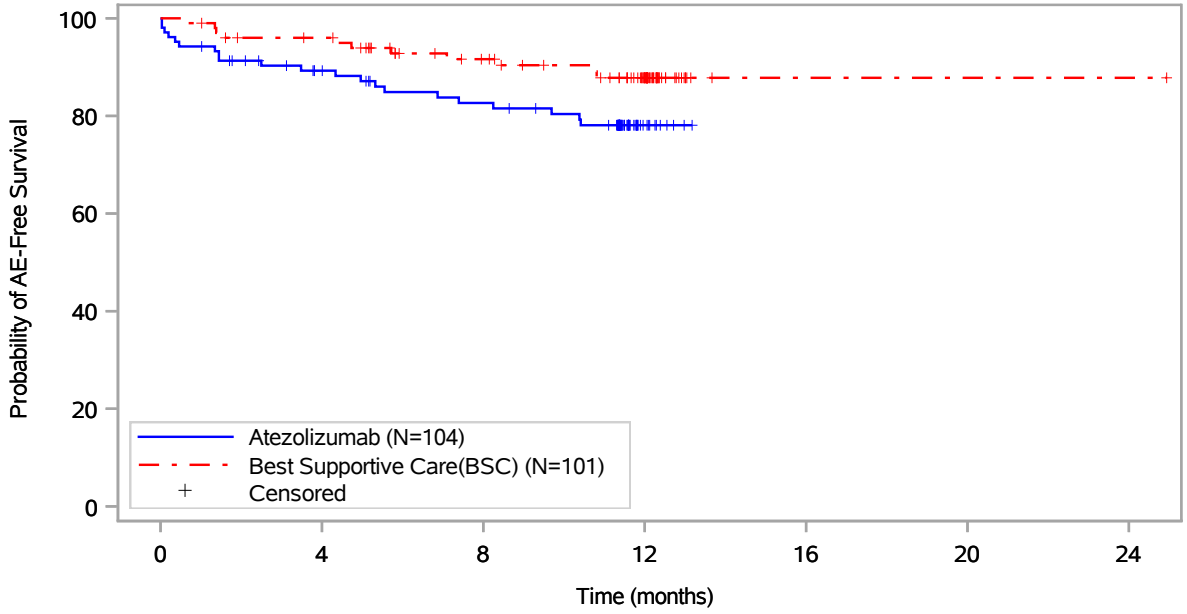


Patients at risk							
Atezolizumab (N=104)	104	18	5	1	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	49	29	13	1	1	1
Patients censored							
Atezolizumab (N=104)	0	0	0	4	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	2	6	17	29	29	29

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..is/ACE_DFS_FA/prod/output/g_km_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
30APR2024 21:01

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



Patients at risk							
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							
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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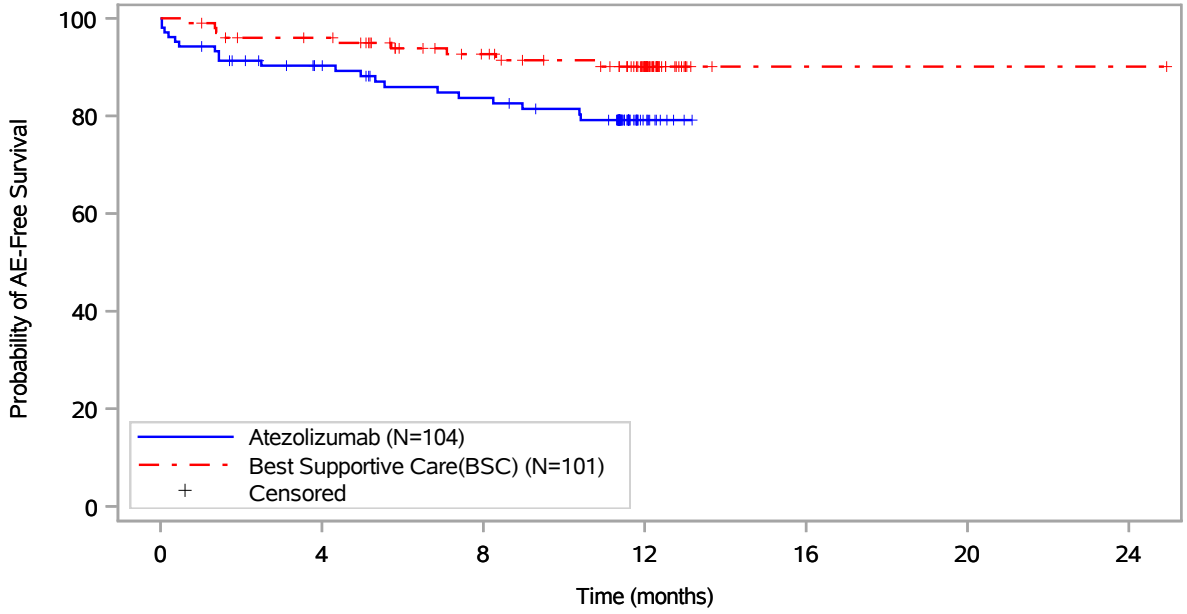
30APR2024 21:04

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



Patients at risk							
Atezolizumab (N=104)	104	85	75	11	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	93	76	49	1	1	1
Patients censored							
Atezolizumab (N=104)	0	9	13	73	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	43	91	91	91

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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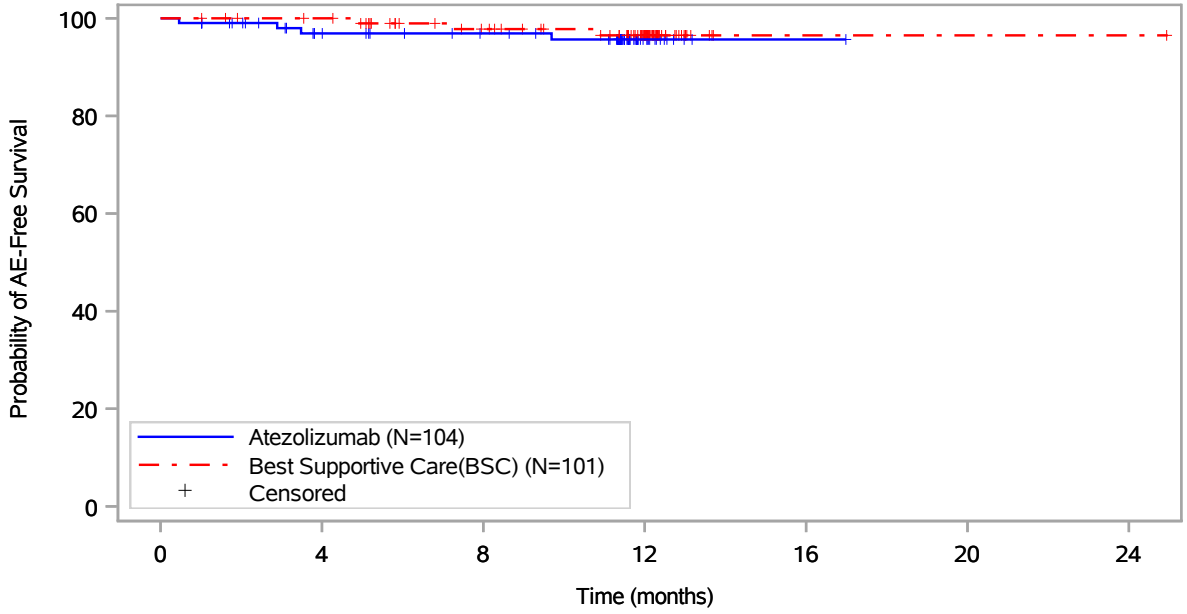
30APR2024 21:07

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

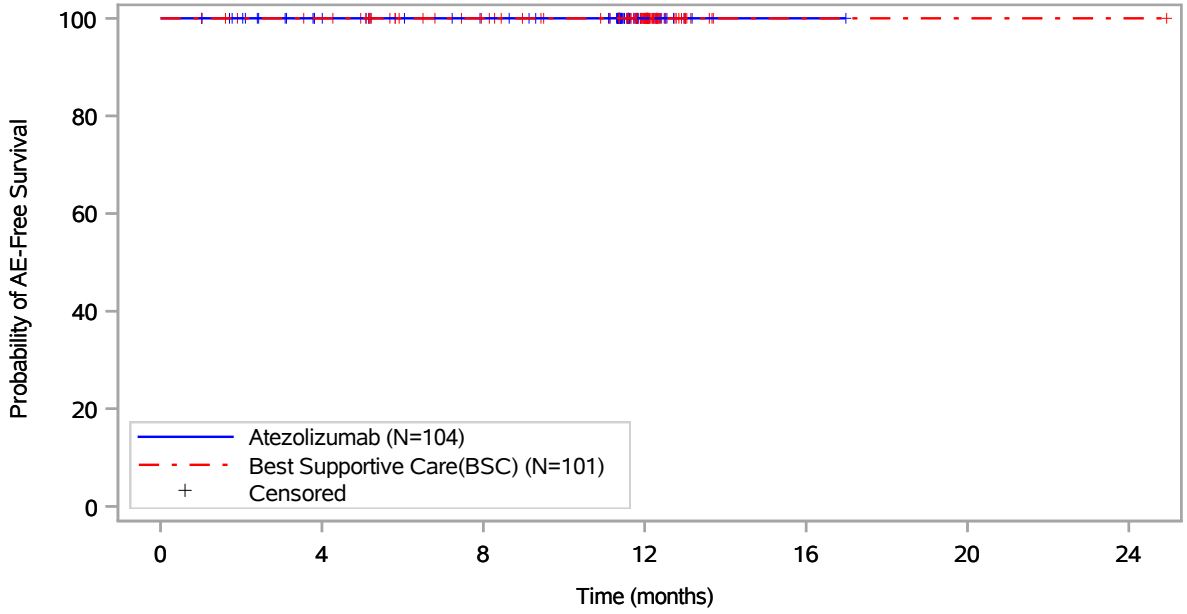


Patients at risk							
Atezolizumab (N=104)	104	87	80	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	54	1	1	1
Patients censored							
Atezolizumab (N=104)	0	14	21	87	99	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	17	44	97	97	97

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
30APR2024 21:10

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

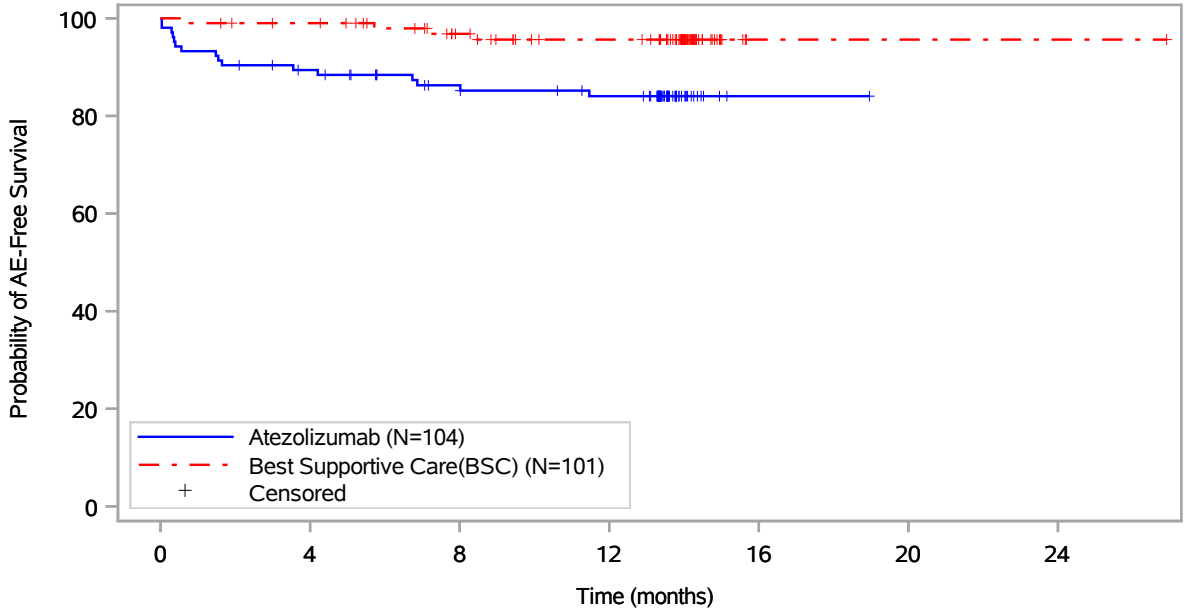


Patients at risk							
Atezolizumab (N=104)	104	89	82	14	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	83	55	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	90	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	18	46	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
30APR2024 21:12

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



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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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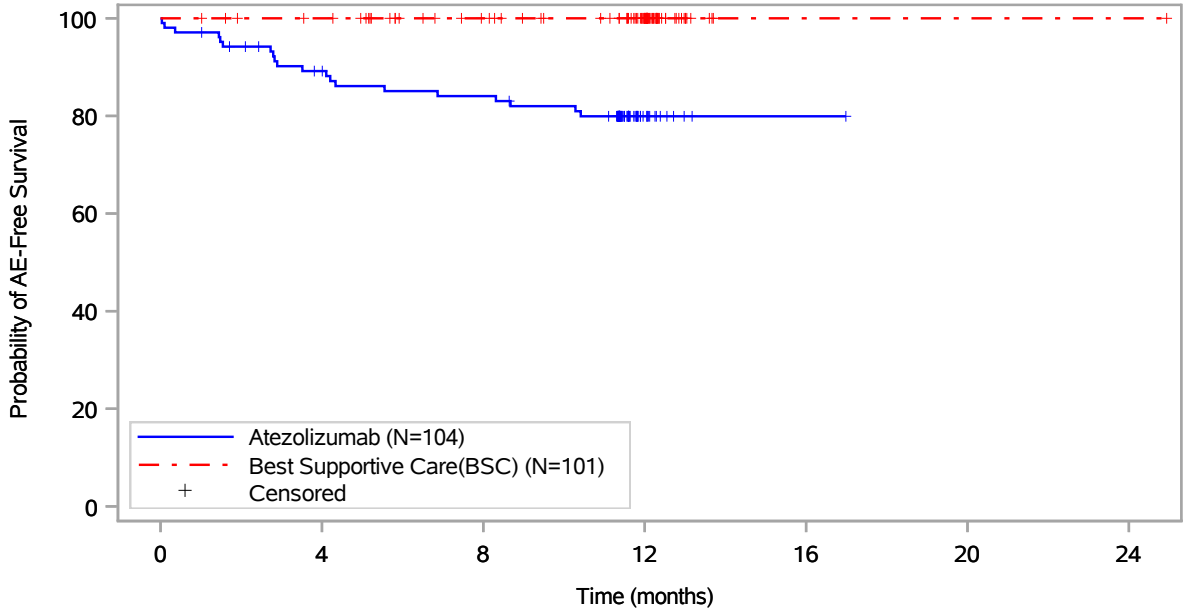
30APR2024 21:14

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA 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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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30APR2024 21:17

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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

	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	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																													
All	575	423	73,6	8	1,4	125	21,7	0	0,0	13	2,3	6	1,0	0	0,0	232	163	70,3	1	0,4	62	26,7	0	0,0	5	2,2	1	0,4	0	0,0
Grade 1	359	275	76,6	4	1,1	71	19,8	0	0,0	6	1,7	3	0,8	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	51	28,7	0	0,0	6	3,4	3	1,7	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	0	0,0	0	0,0	1	33,3	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	0	0,0	0	0,0	2	28,6	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	0	0,0	0	0,0	1	100,0	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_resolved.sas
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02MAY2024 14:04

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Verträglichkeit

Generelle Verträglichkeit nach SOC/PT

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 that occurred in at least 10 patients in a study arm
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
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	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
Gastrointestinal disorders		n/a	104	100,0	23	22,1	81	77,9	101	100,0	12	11,9	89	88,1	0,0369	2,07	1,03	4,17		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	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
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	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
Investigations		n/a	104	100,0	34	32,7	70	67,3	101	100,0	9	8,9	92	91,1	<.0001	4,46	2,14	9,33		Convergence criterion (GCONV=1E-8) satisfied.	NE
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
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
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
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	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
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	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

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:25

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 Adverse Event that occurred in at least 10 patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Sex per eCRF

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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.	
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	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.	
Gastrointestinal disorders		Male	82	78,8	17	20,7	65	79,3	71	70,3	7	9,9	64	90,1	0,0486	2,36	0,98	5,71		Convergence criterion (GCONV=1E-8) satisfied.	0,7876
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.	
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	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.	
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	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.	
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	16,49		Convergence criterion (GCONV=1E-8) satisfied.	0,1055
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.	
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.	
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.	
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.	
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	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.	
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	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.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_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 that occurred in at least 10 patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Age at Randomization

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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.	
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	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.	
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.	0,1559
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.	
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	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.	
Infections and infestations		< 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
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	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.	
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	9,31		Convergence criterion (GCONV=1E-8) satisfied.	0,6024
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.	
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
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.	
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.	
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.	
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
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	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.	
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	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.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_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 that occurred in at least 10 patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Geographic 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	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.	
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	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.	
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.	0,5837
Gastrointestinal disorders		Europe and Middle East	65	62,5	11	16,9	54	83,1	68	67,3	8	11,8	60	88,2	0,3326	1,56	0,63	3,90		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.	
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.	
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.	
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	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.	
Investigations		Asia Pacific and Australia	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.	0,1762
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	14,52		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.	
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
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.	
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.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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	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.	
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.	
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.	
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	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.	0,7456
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.	
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	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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:25

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 Adverse Event that occurred in at least 10 patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Tumor stage per eCRF

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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.	0,9633
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.	
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	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.	
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.	
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	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.	
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.	
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.	
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.	
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.	
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.	
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.	

Vollständige Darstellung relevanter Ergebnisse

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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	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.	
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.	
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	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.	
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	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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:25

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 Grade 3-5 Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTGR35AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:32

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 that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTGR3AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:38

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 Grade 4 Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTGR4AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:45

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 5 Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTGR5AE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:51

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 Serious Adverse Event that occurred in at least 5% of patients in a study arm
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)
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

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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte_soc.saas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:56

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 Serious Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Sex per eCRF

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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	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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:56

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 Serious Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Age at Randomization

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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	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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:56

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 Serious Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Geographic 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)
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
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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:56

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 Serious Adverse Event that occurred in at least 5% of patients in a study arm
MODEL: Unstratified analysis
STUDY: GO29527
Time to Event Analysis by Subgroups (Safety)

Tumor stage per eCRF

			Atezolizumab (N=104)						Best Supportive Care(BSC) (N=101)						Atezolizumab vs. Best Supportive Care(BSC)						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred 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		IIA	31	29,8	0	0,0	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.	

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: 26JAN2024

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_FA/prod/output/t_ae_tte_soc_sg_TTSAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:56

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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 >= 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	%
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
Gastrointestinal disorders		n/a	104	100,0	1	1,0	101	100,0	0	0
Gastrointestinal 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	1	1,0	101	100,0	0	0
Immune system disorders	Hypersensitivity	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
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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:17

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA 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)

Sex per eCRF

			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
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
Gastrointestinal disorders		Male	82	78,8	1	1,2	71	70,3	0	0
Gastrointestinal disorders		Female	22	21,2	0	0,0	30	29,7	0	0
Gastrointestinal disorders	Colitis	Male	82	78,8	1	1,2	71	70,3	0	0
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	1	1,2	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
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
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
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

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)		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
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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_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: AEs leading to Atezolizumab Discontinuation
MODEL: Unstratified analysis
STUDY: GO29527
Dichotomous Analysis by Subgroups (Safety)

Age at Randomization

			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		>= 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	>= 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		>= 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
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	1	1,6	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
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
Investigations	Alanine aminotransferase increased	>= 65	40	38,5	0	0,0	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
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
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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
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POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA 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)

Geographic 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 Australia	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 Australia	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
Cardiac disorders		Asia Pacific and Australia	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 Australia	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 Australia	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
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
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
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
Immune system disorders		Asia Pacific and Australia	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	Hypersensitivity	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0
Immune system disorders	Hypersensitivity	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Immune system disorders	Hypersensitivity	North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations		Asia Pacific and Australia	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

			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		North America	10	9,6	0	0,0	10	9,9	0	0
Infections and infestations	Encephalitis	Asia Pacific and Australia	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 Australia	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 Australia	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 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	1	1,5	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
Investigations	Blood creatinine increased	Asia Pacific and Australia	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 Australia	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 Australia	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 Australia	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 Australia	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 Australia	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 Australia	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_WDAE_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
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POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA 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)

Tumor stage per eCRF

			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
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
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
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
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

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		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
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	1	2,2	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
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
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
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: 26JAN2024

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30APR2024 20:17

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Verträglichkeit

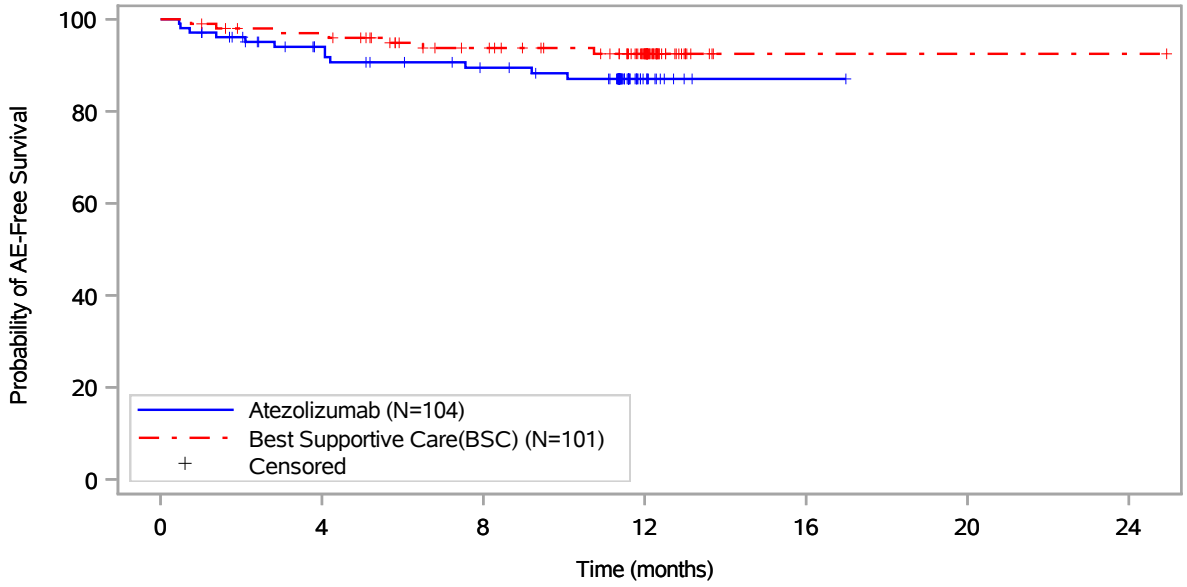
Generelle Verträglichkeit nach SOC/PT

KM Plots

Unstratifiziert

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, 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: 26JAN2024

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30APR2024 23:22

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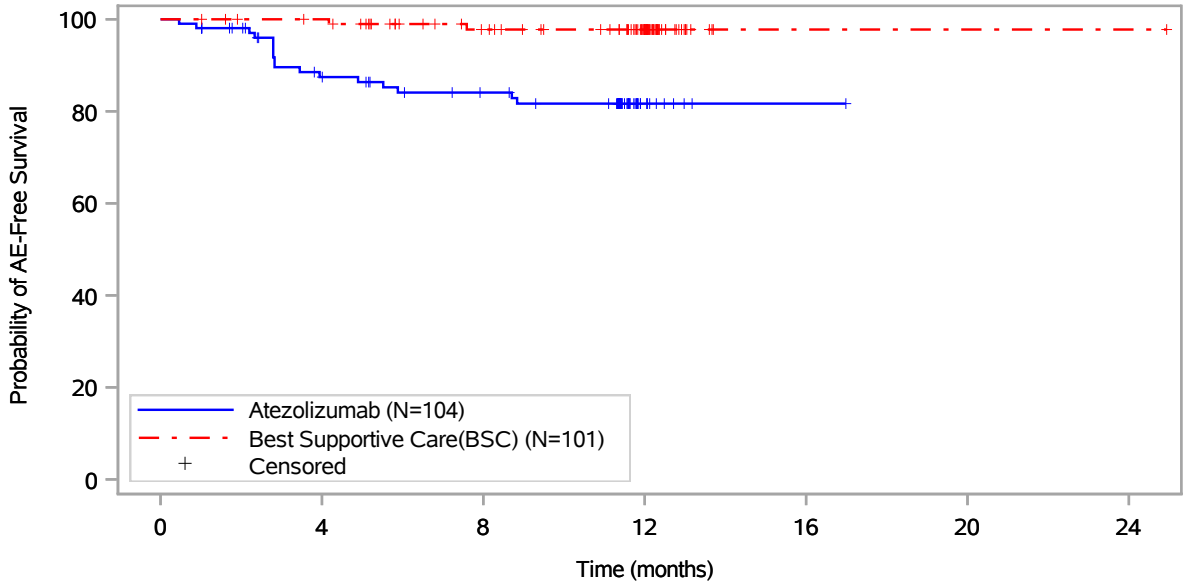
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Endocrine disorders, All



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: 26JAN2024

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30APR2024 23:22

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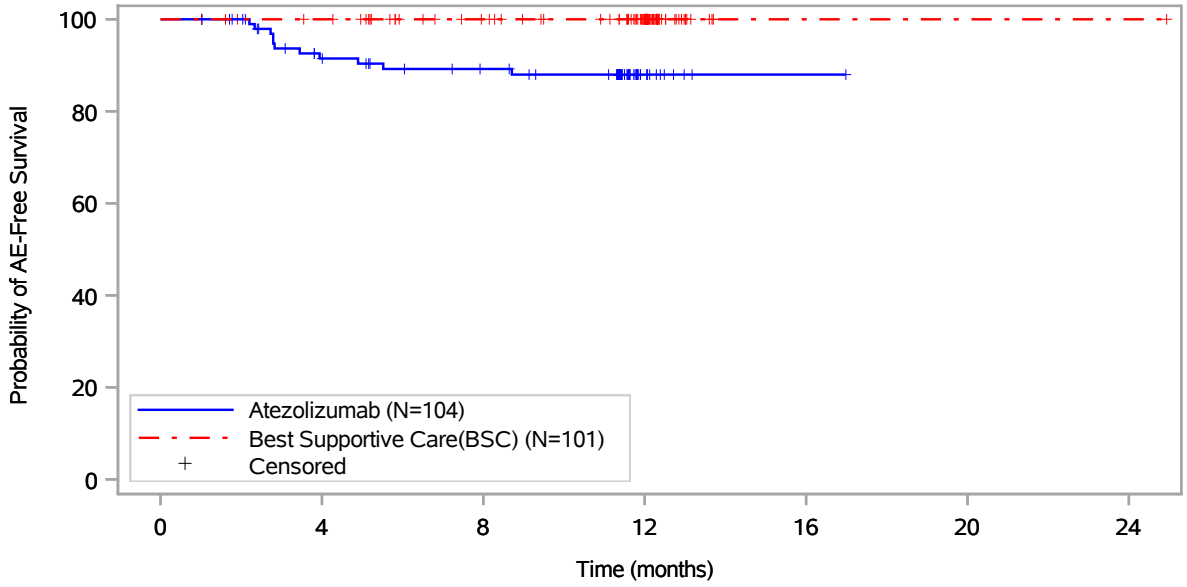
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Endocrine disorders, Hypothyroidism



Patients at risk							
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							
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: 26JAN2024

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30APR2024 23:22

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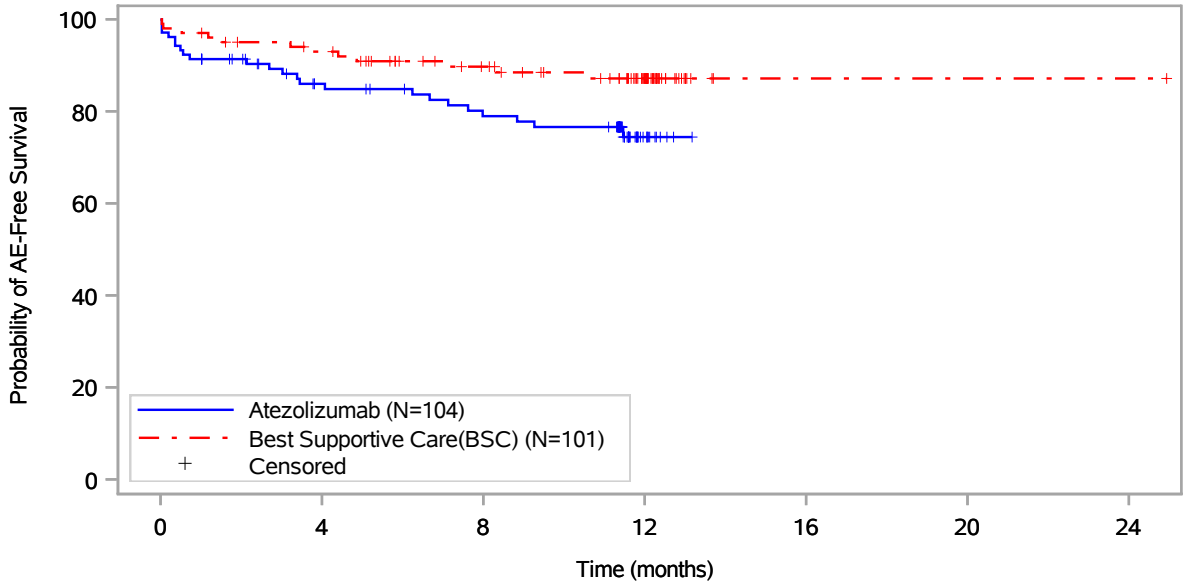
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Gastrointestinal disorders, All



Patients at risk							
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							
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: 26JAN2024

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30APR2024 23:22

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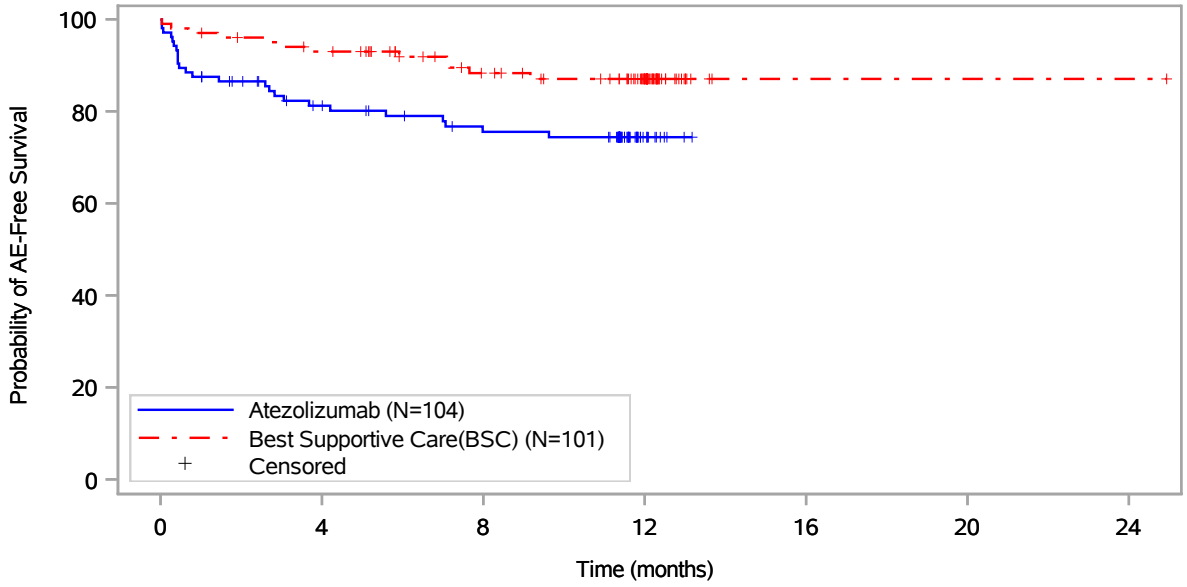
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, All



Patients at risk							
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							
Atezolizumab (N=104)	0	10	15	68	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	17	42	88	88	88

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 23:22

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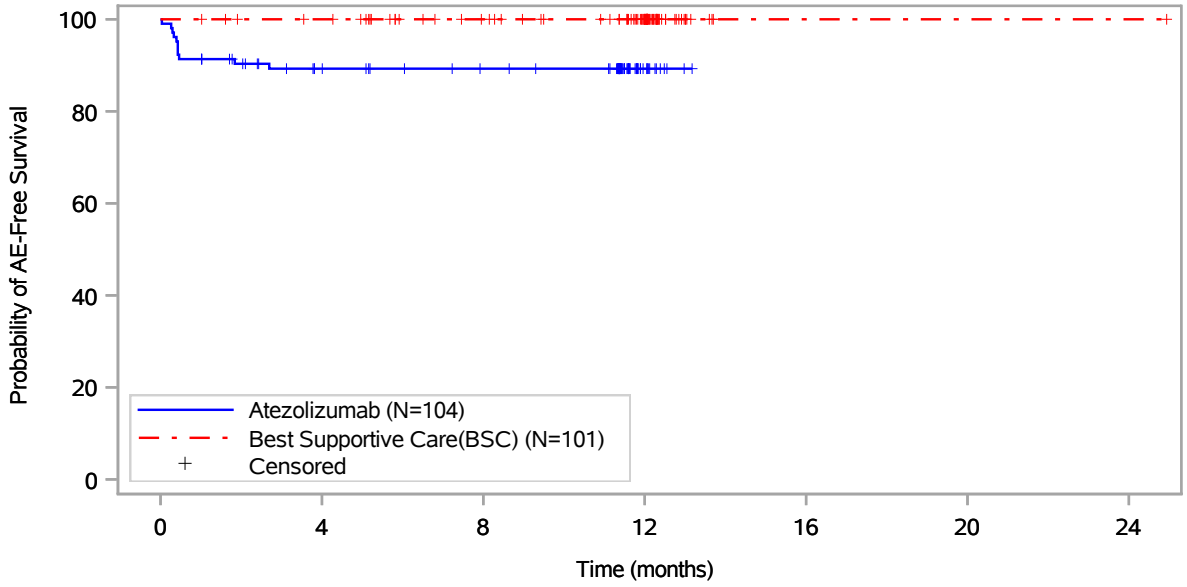
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

General disorders and administration site conditions, Pyrexia



Patients at risk							
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							
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: 26JAN2024

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30APR2024 23:22

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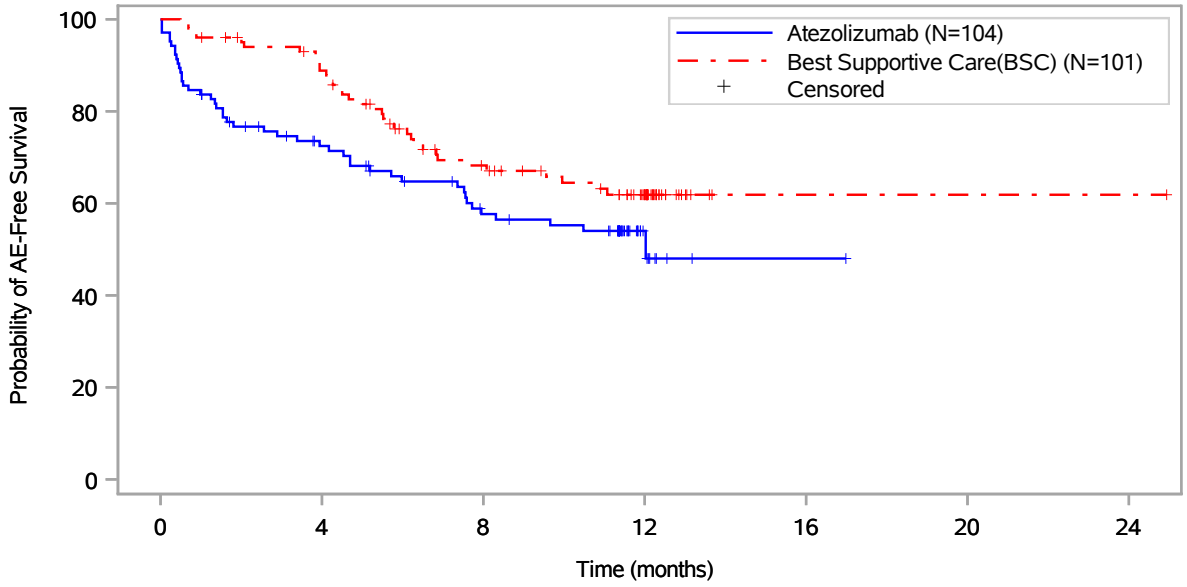
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Infections and infestations, All



Patients at risk							
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: 26JAN2024

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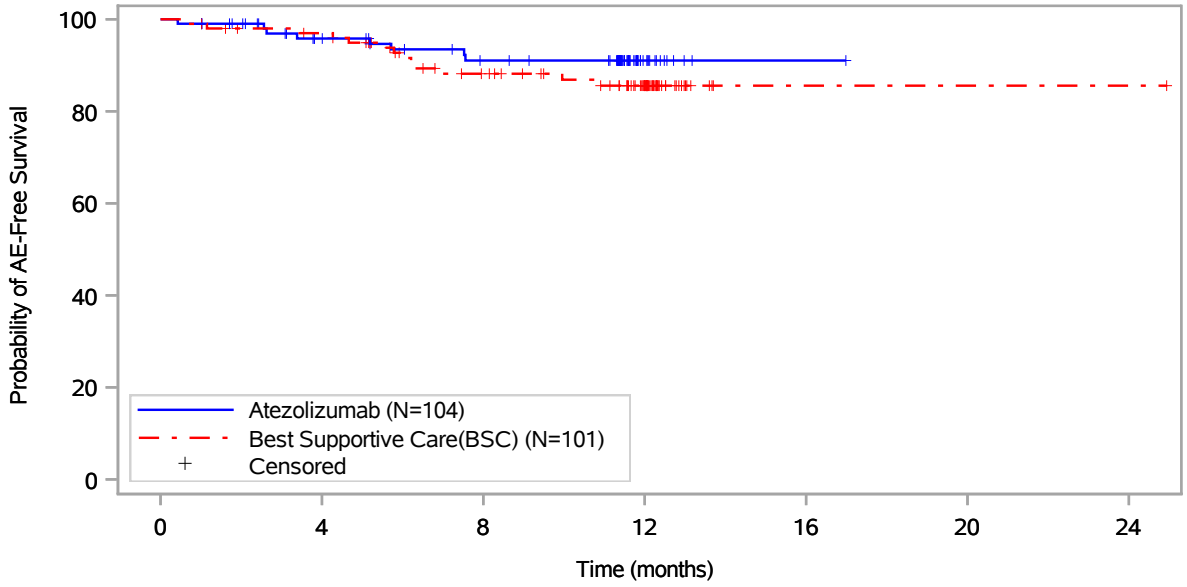
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Infections and infestations, Nasopharyngitis



Patients at risk							
Atezolizumab (N=104)	104	85	74	13	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	94	74	47	1	1	1
Patients censored							
Atezolizumab (N=104)	0	15	22	83	95	NE	NE
Best Supportive Care(BSC) (N=101)	0	4	16	41	87	87	87

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

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30APR2024 23:22

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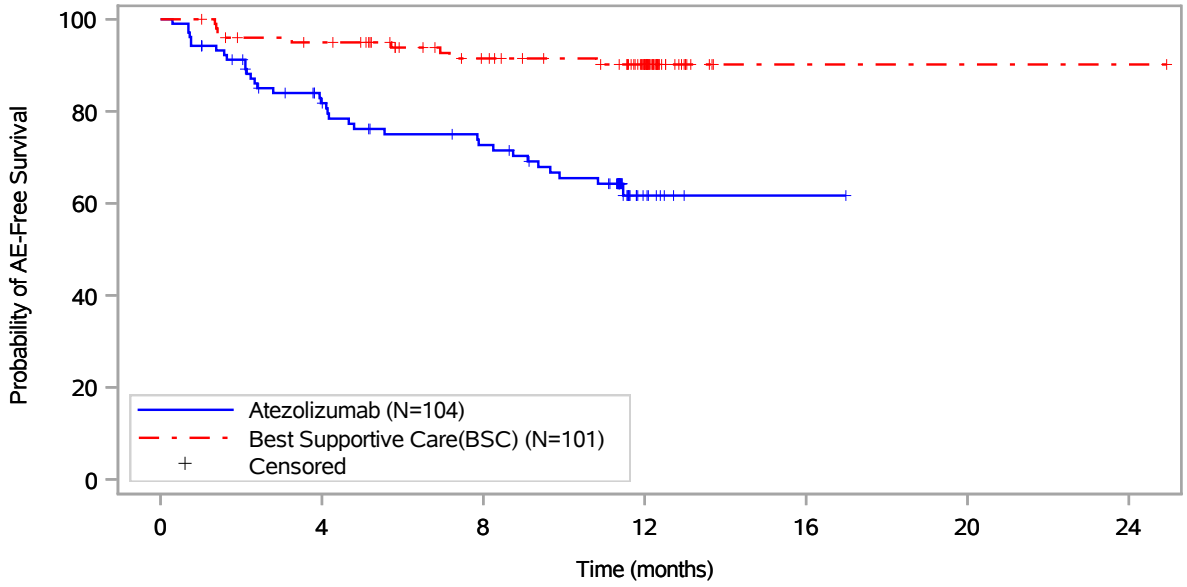
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Investigations, All



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: 26JAN2024

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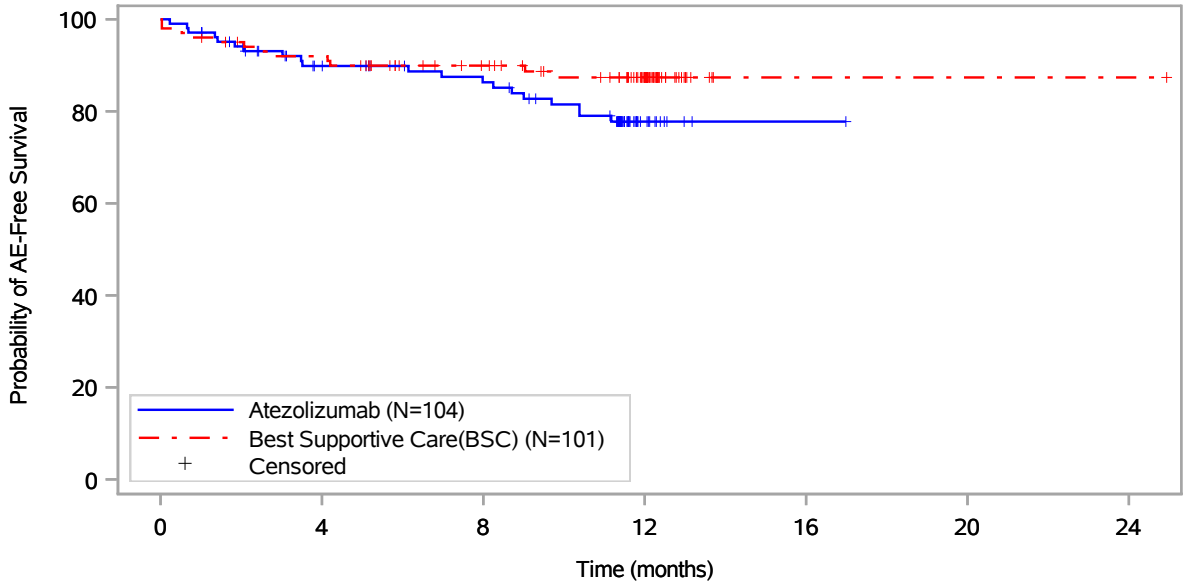
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Metabolism and nutrition disorders, All



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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 23:22

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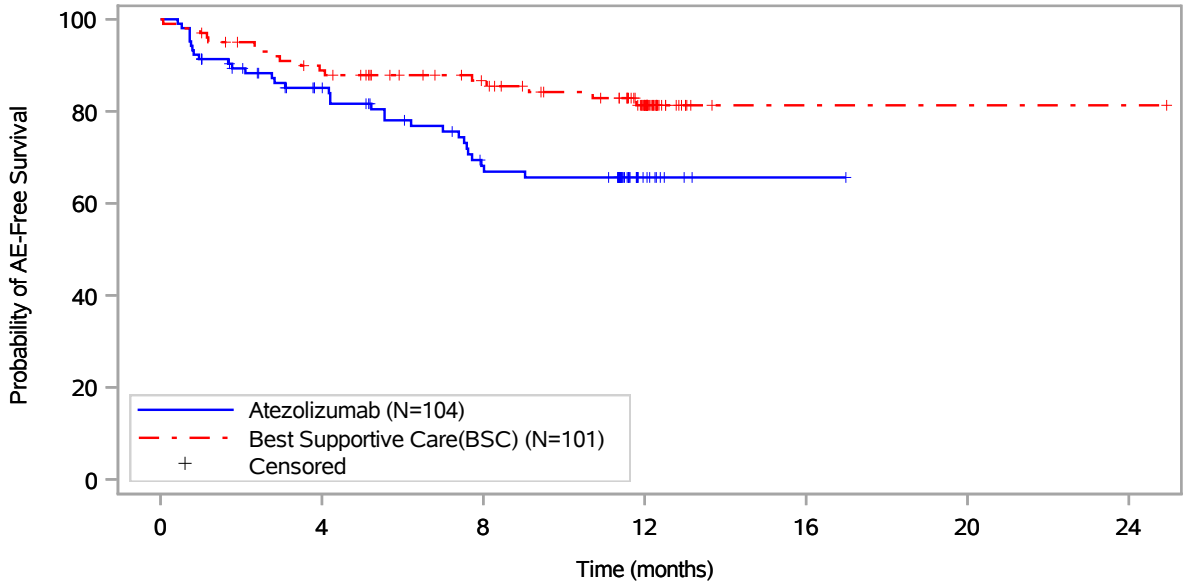
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Musculoskeletal and connective tissue disorders, All



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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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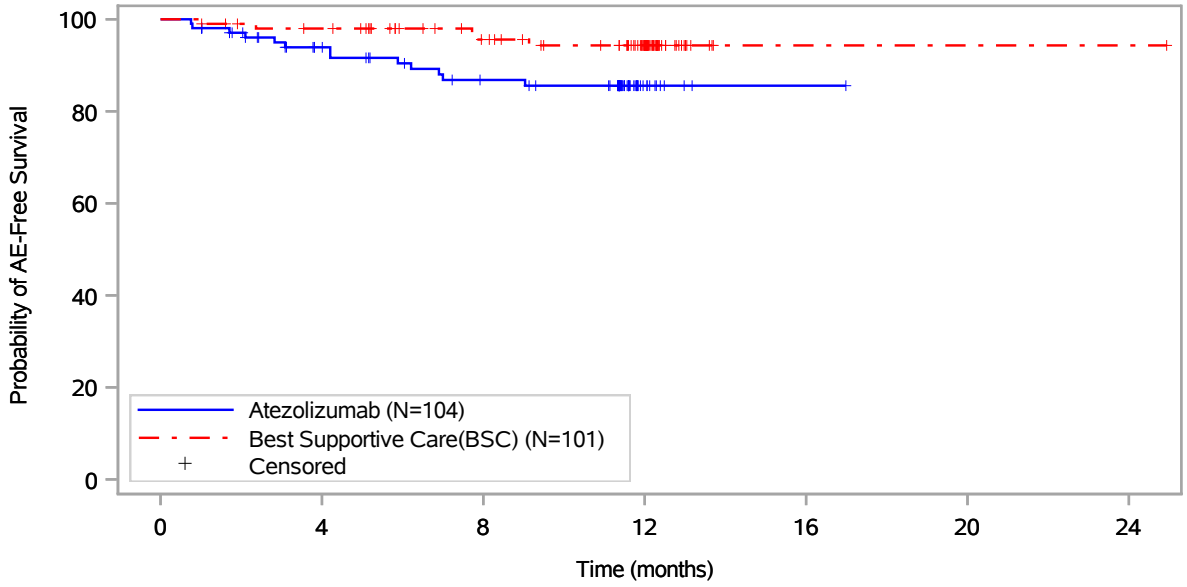
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

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: 26JAN2024

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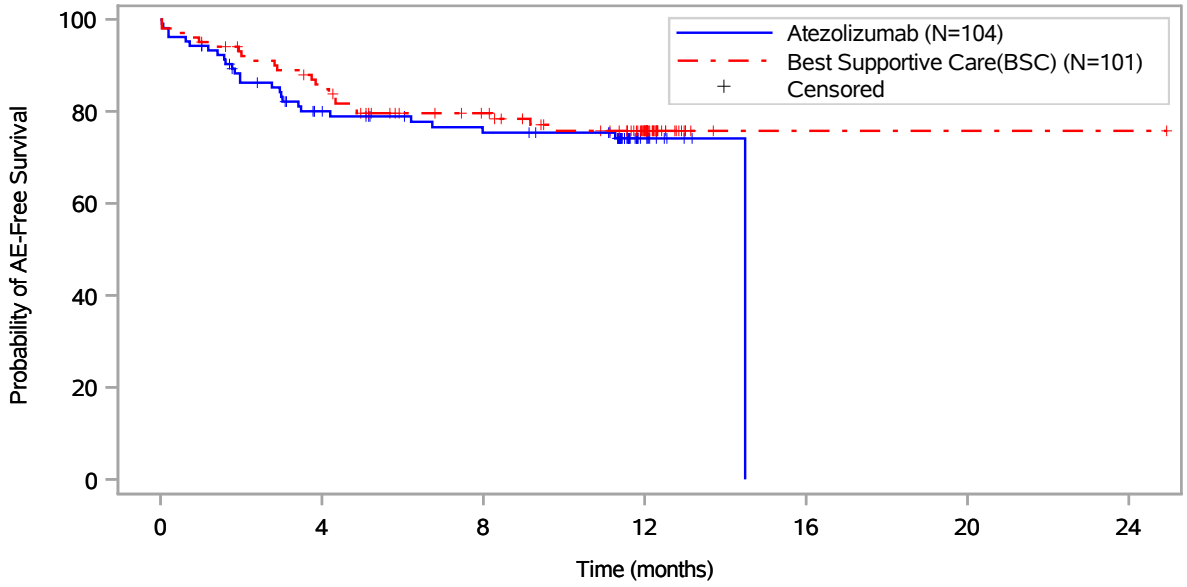
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527
Nervous system disorders, All



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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 23:22

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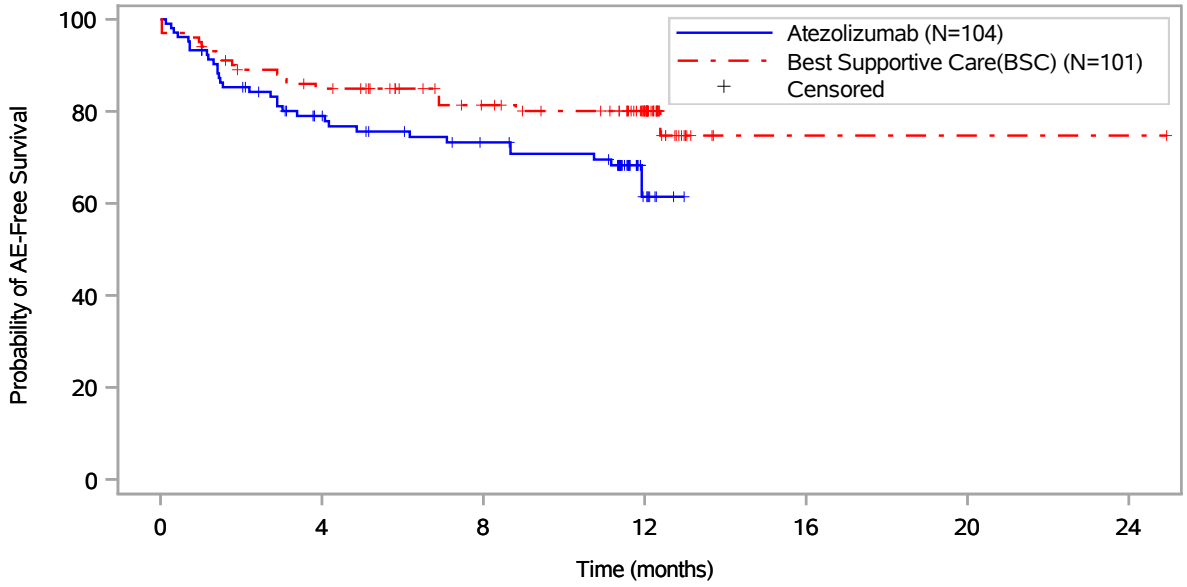
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, All



Patients at risk							
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							
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: 26JAN2024

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30APR2024 23:22

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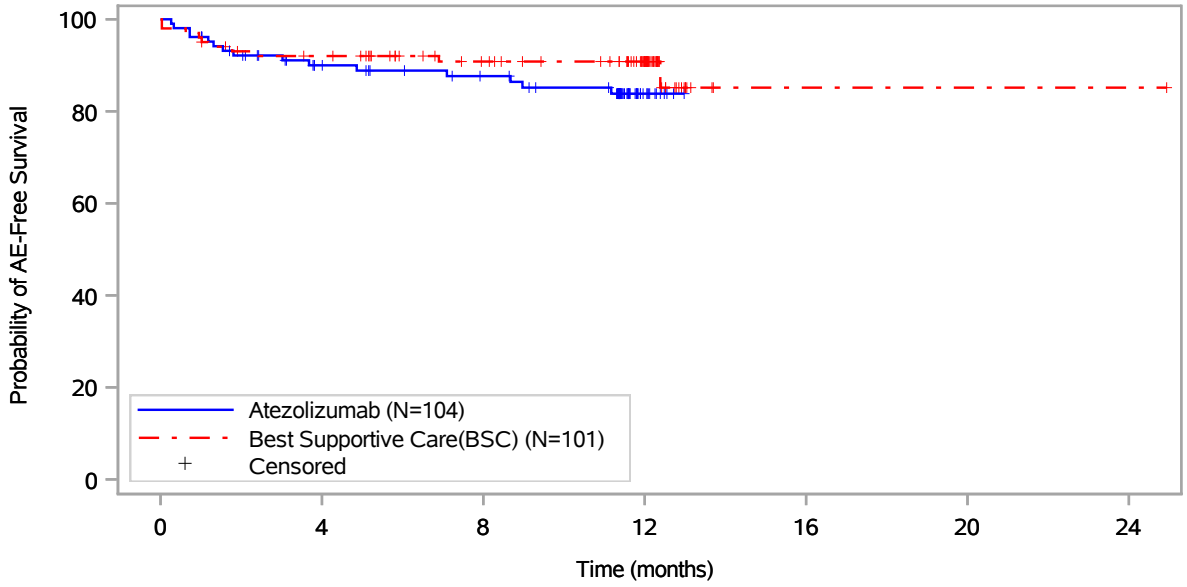
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Respiratory, thoracic and mediastinal disorders, Cough



Patients at risk							
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							
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: 26JAN2024

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30APR2024 23:22

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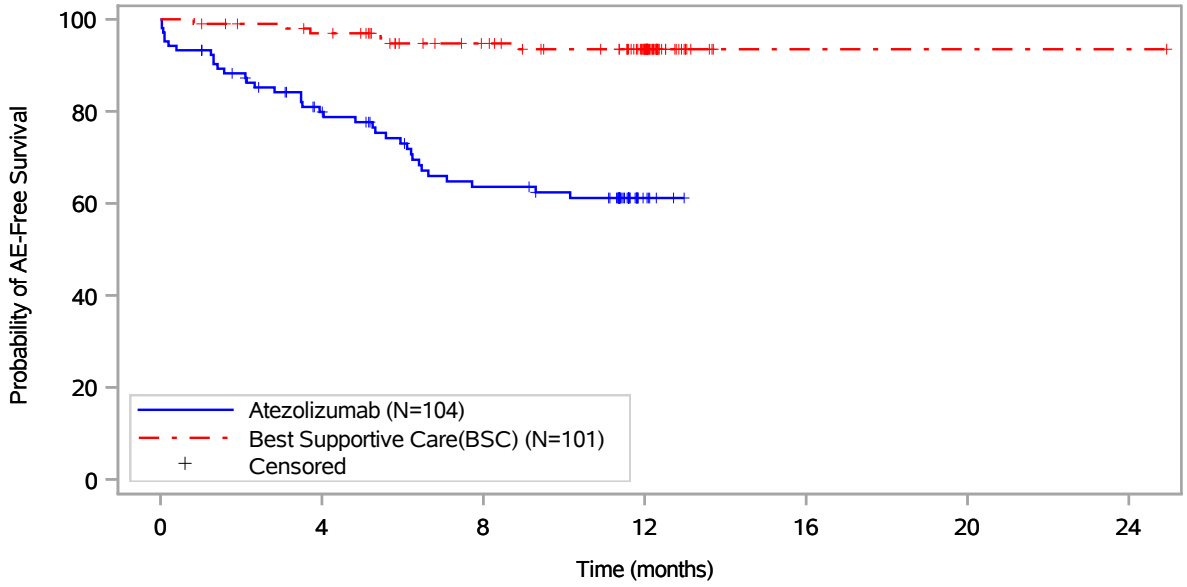
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Skin and subcutaneous tissue disorders, All



Patients at risk							
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							
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 23:22

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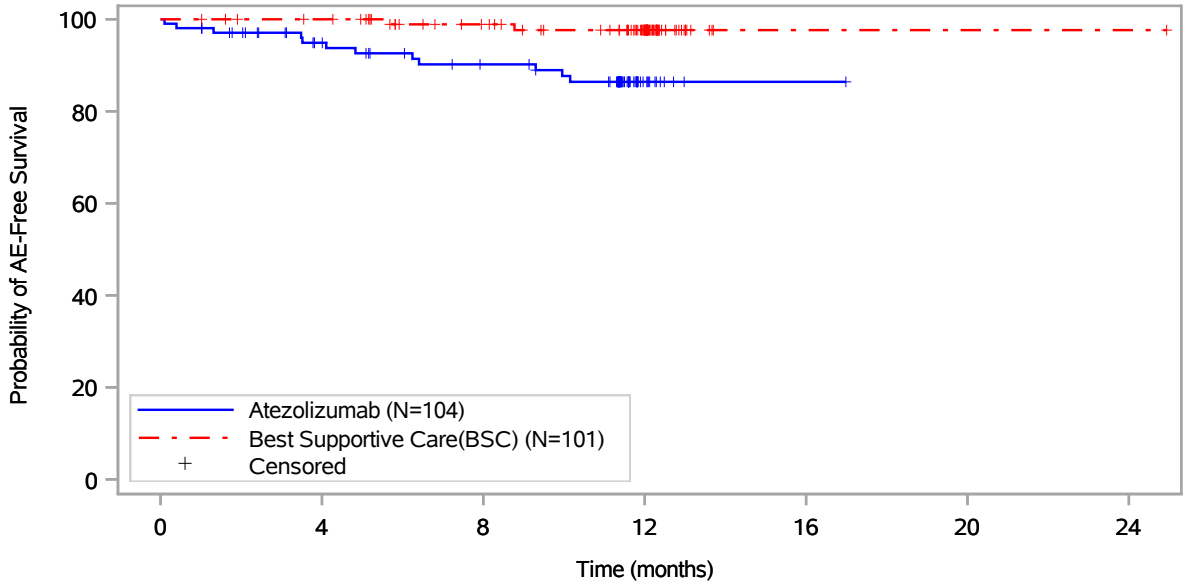
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

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: 26JAN2024

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30APR2024 23:22

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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 that occurred in at least 5% of patients in a study arm
STUDY: GO29527

Null Report: No results could be derived for this output.

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 23:57

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 that occurred in at least 5% of patients in a study arm
STUDY: GO29527

Null Report: No results could be derived for this output.

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

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01MAY2024 0:01

Vollständige Darstellung 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 that occurred in at least 5% of patients in a study arm
STUDY: GO29527

Null Report: No results could be derived for this output.

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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01MAY2024 0:06

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Grade 5 Adverse Event that occurred in at least 5% of patients in a study arm
STUDY: GO29527

Null Report: No results could be derived for this output.

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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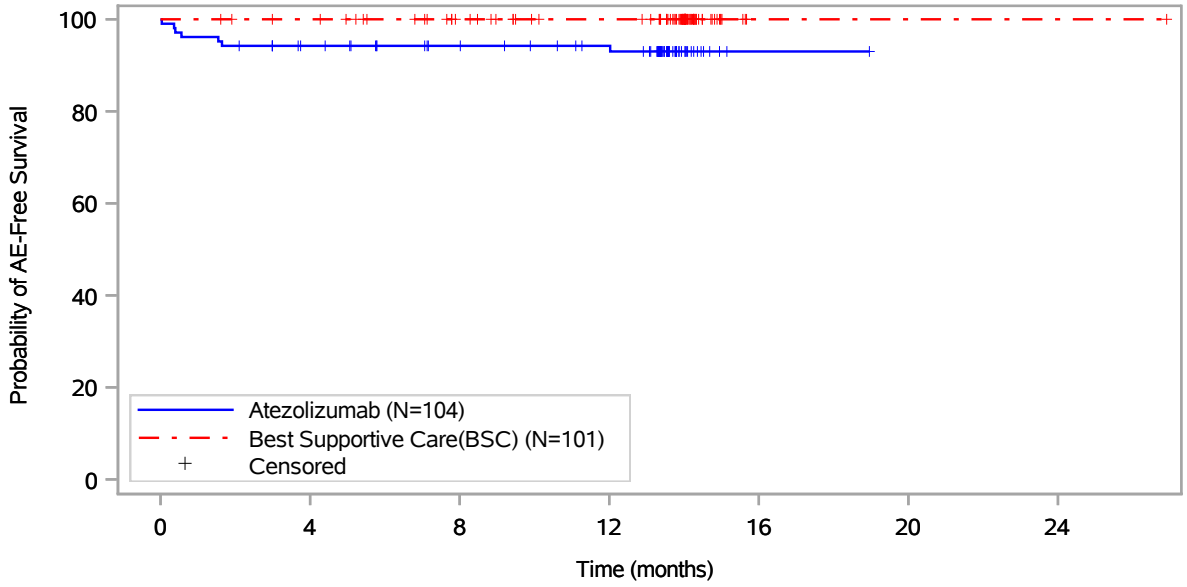
01MAY2024 0:11

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, 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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01MAY2024 0:14

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Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Verträglichkeit

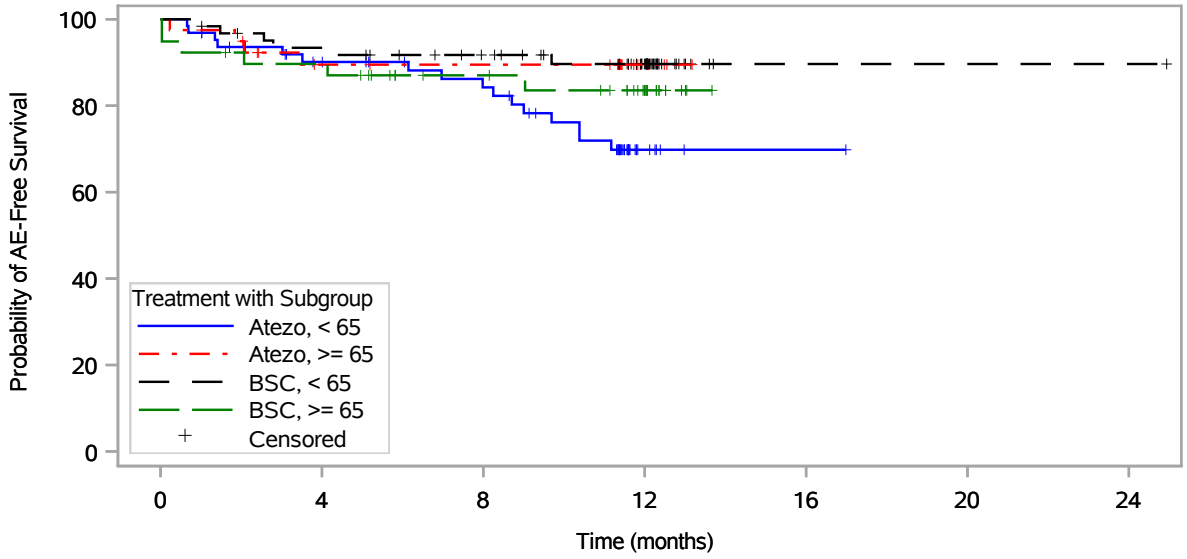
Generelle Verträglichkeit nach SOC/PT

KM Plots

Subgruppen

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; Metabolism and nutrition disorders, All (N=205)



Patients at risk							
Atezo, < 65	64	50	43	6	1	NE	NE
Atezo, >= 65	40	31	30	5	NE	NE	NE
BSC, < 65	62	56	49	33	1	1	1
BSC, >= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 22:28

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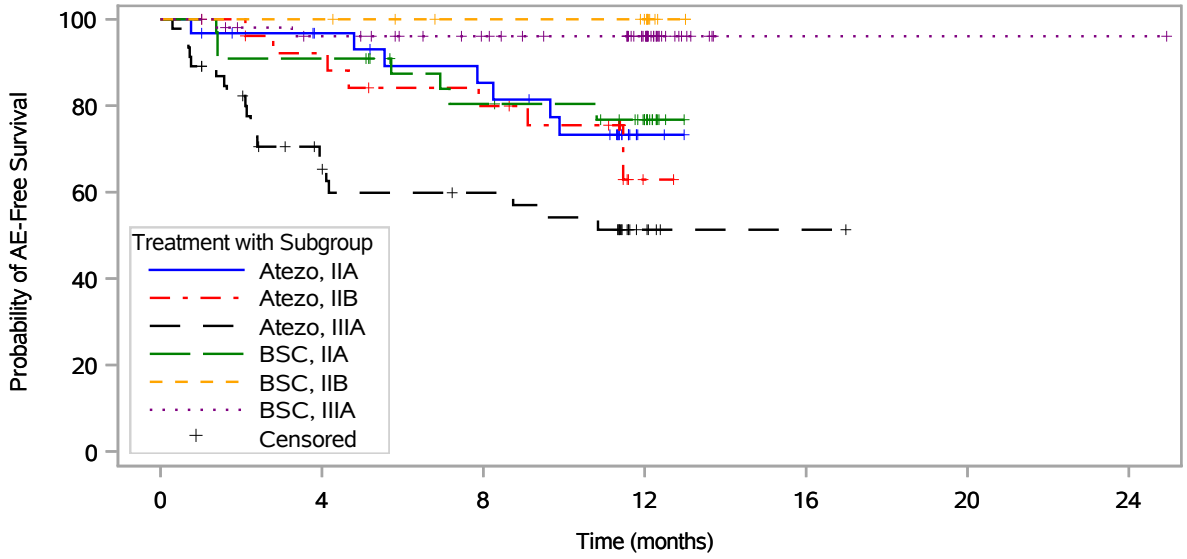
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Tumor stage; Investigations, All (N=205)



Patients at risk							
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 22:28

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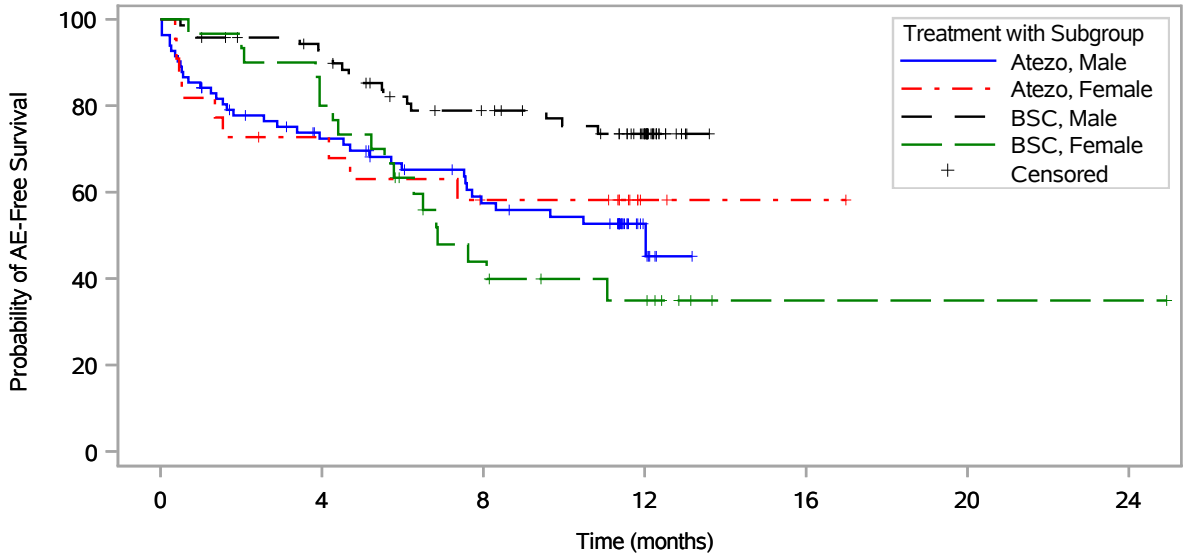
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Infections and infestations, All (N=205)



Patients at risk							
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 22:28

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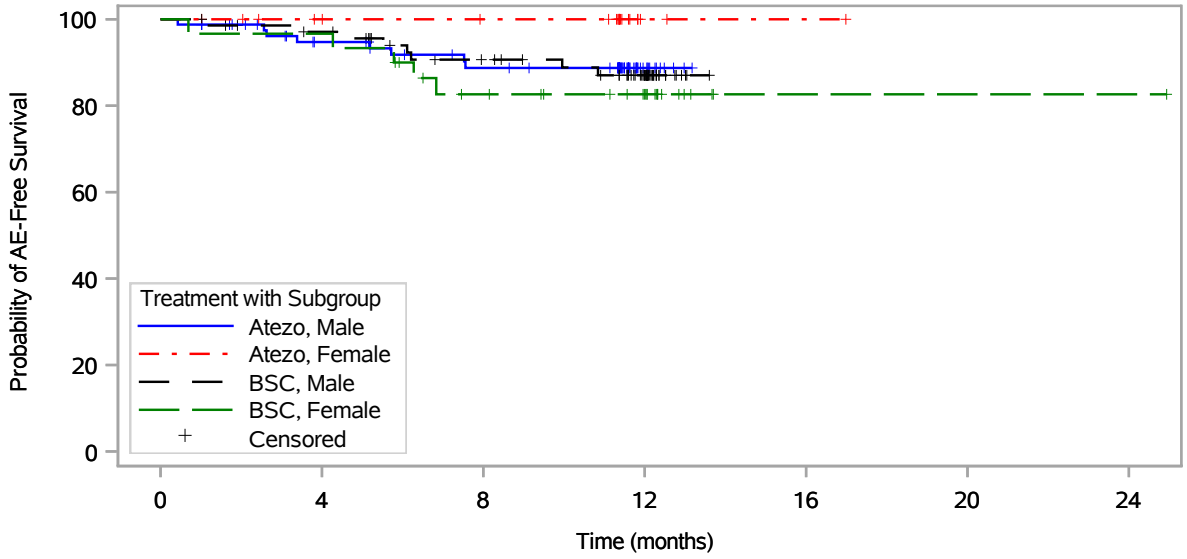
POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Adverse Event
STUDY: GO29527

Sex; Infections and infestations, Nasopharyngitis (N=205)



Patients at risk							
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/g_km_soc.sas
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30APR2024 22:28

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Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Verträglichkeit

Spezifische Verträglichkeit

Operationalisierung der Adverse Events of Special Interest (AESI)

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 erythrodysaesthesia 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)

AESI	Reference Type (MedDRA v23.1)	Methodology
Immune-Mediated Guillan-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, Adrenocorticotropic 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

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

Aktueller Datenschnitt vom 26.01.2024

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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMRH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:48

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMRH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:51

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 Rash 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMRHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:54

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 Immune-Mediated Hepatitis
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	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	0,3024	>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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:58

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 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)						
		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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHP35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:00

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHPS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:03

Vollständige Darstellung 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: 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	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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:06

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 Immune-Mediated Hypothyroidism 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLT35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:09

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 Hypothyroidism 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:12

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:15

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHT35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:19

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMHTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:22

Vollständige Darstellung 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPN_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:35

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPN35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:38

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPNS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:41

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMSR_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:55

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMSR35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:58

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 Severe Cutaneous Reactions 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMSRS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:01

Vollständige Darstellung 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMME_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:49

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMME35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:52

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMES_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:54

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMI_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:04

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMI35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:08

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMIS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:11

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMEP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:14

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:16

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMEPS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:43

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMCL35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:46

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 Colitis 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:49

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMGB_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:52

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMGB35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:54

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 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMGBS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:57

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 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	96,3	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:23

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 Ocular Inflammatory Toxicity 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMOT35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:26

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 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 Autoimmune Hemolytic Anemia
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTAHA_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:03

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTAHA35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:06

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 Autoimmune Hemolytic Anemia 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTAHAS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 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
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMAI_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:25

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 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMAI35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 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 Adrenal insufficiency 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMAIS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:32

Vollständige Darstellung 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 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			
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMDM_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:13

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMDM35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:16

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: 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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMDMS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:19

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:40

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:43

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMLHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:45

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 Myocarditis
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMC_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:48

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 Myocarditis 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMC35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:50

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMCS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:53

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMG_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:00

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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMG35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:03

Vollständige Darstellung 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					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			
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMGS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 22:06

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 Immune-Mediated Myositis
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMY_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:22

Vollständige Darstellung 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					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			
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMY35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:25

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 Myositis 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMMYS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 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 Nephritis
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMNP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:40

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMNP35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:43

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 Nephritis 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	0	0	104	100,0	101	100,0	0	0	101	100,0	NE	NE	NE	NE			
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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMNPS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:46

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 Pancreatitis
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPC_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:05

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPC35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:08

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 Pancreatitis 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMPCS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:11

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: 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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMVS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:32

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMVS35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:34

Vollständige Darstellung 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIMVSS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:37

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 Infusion-Related 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 20:57

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIRR35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:00

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 Infusion-Related Reactions 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	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTIRRS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:02

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 Rhabdomyolysis
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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_ae_tte_sg_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
30APR2024 21:31

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 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					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
	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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
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30APR2024 21:34

Vollständige Darstellung 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: 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
	>= 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: 26JAN2024

Program: root/global/globalshare/morse_macros/current/prod/program/t_ae_tte.sas
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30APR2024 21:37

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

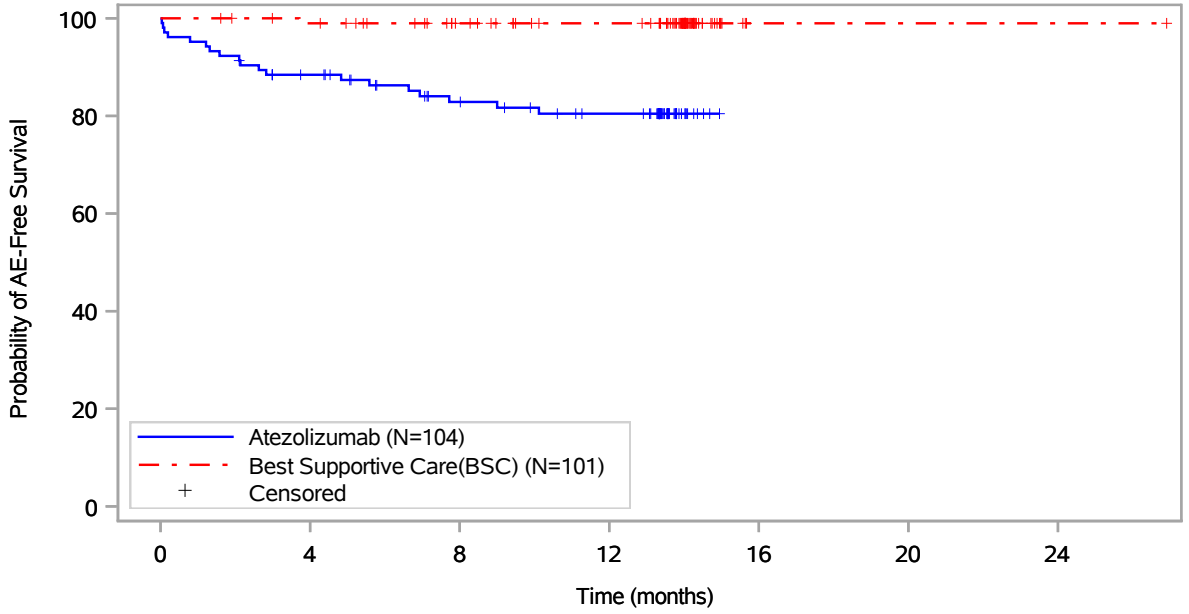
Verträglichkeit

Spezifische Verträglichkeit

KM Plots

Unstratifiziert

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
STUDY: GO29527

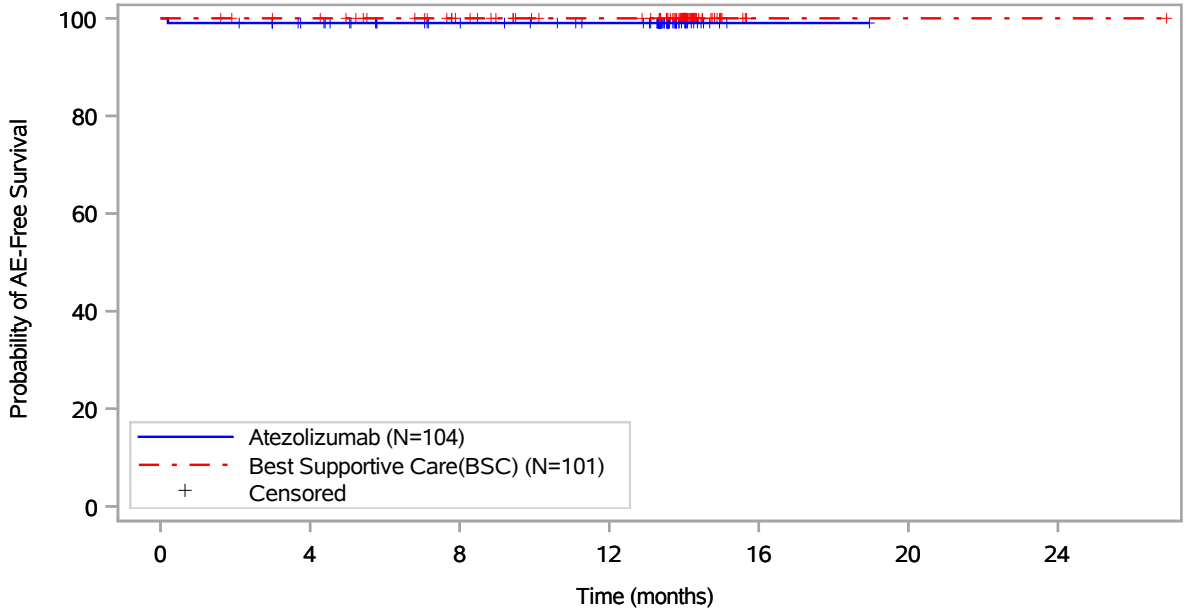


Patients at risk							
Atezolizumab (N=104)	104	86	71	63	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	85	76	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	16	22	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	99	99	99

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMRH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:47

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
STUDY: GO29527

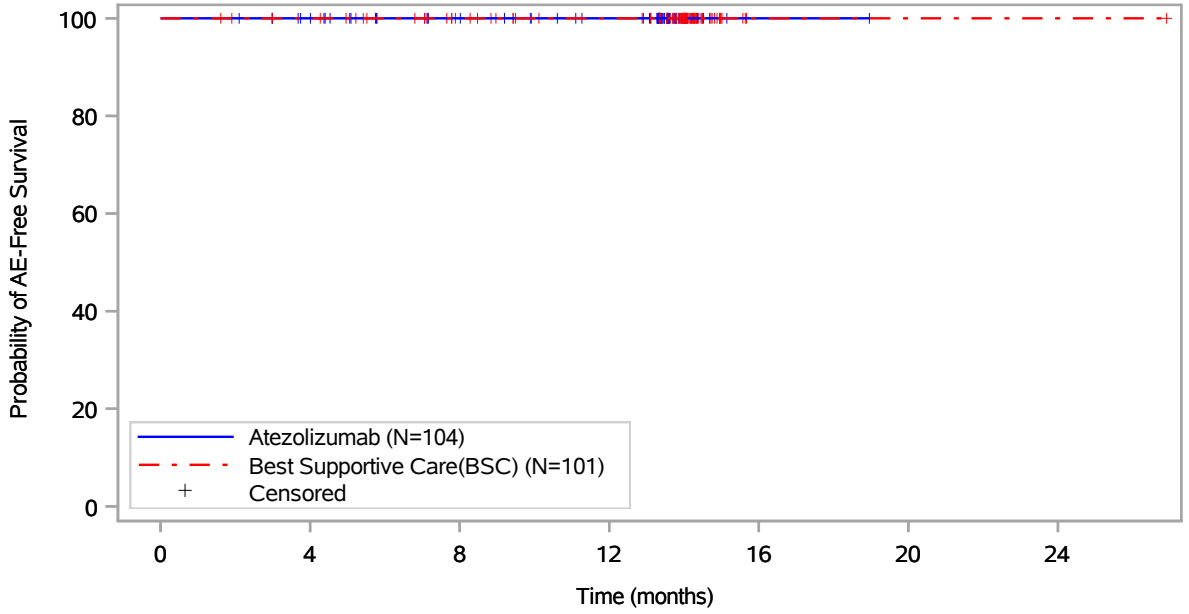


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMRH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:52

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
STUDY: GO29527

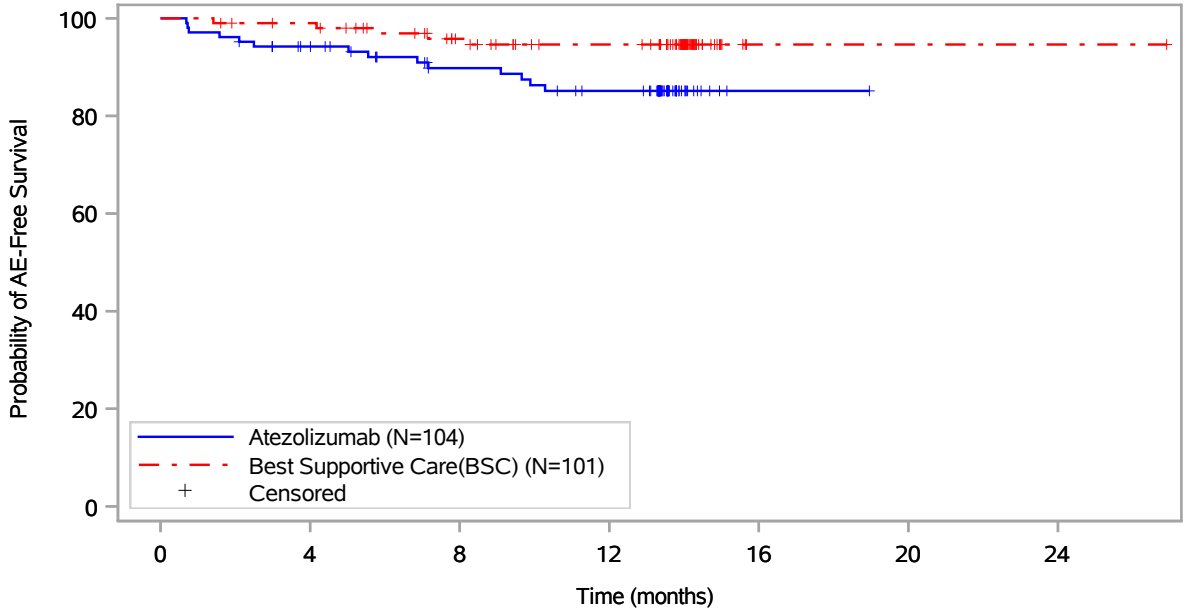


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMRHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:57

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
STUDY: GO29527

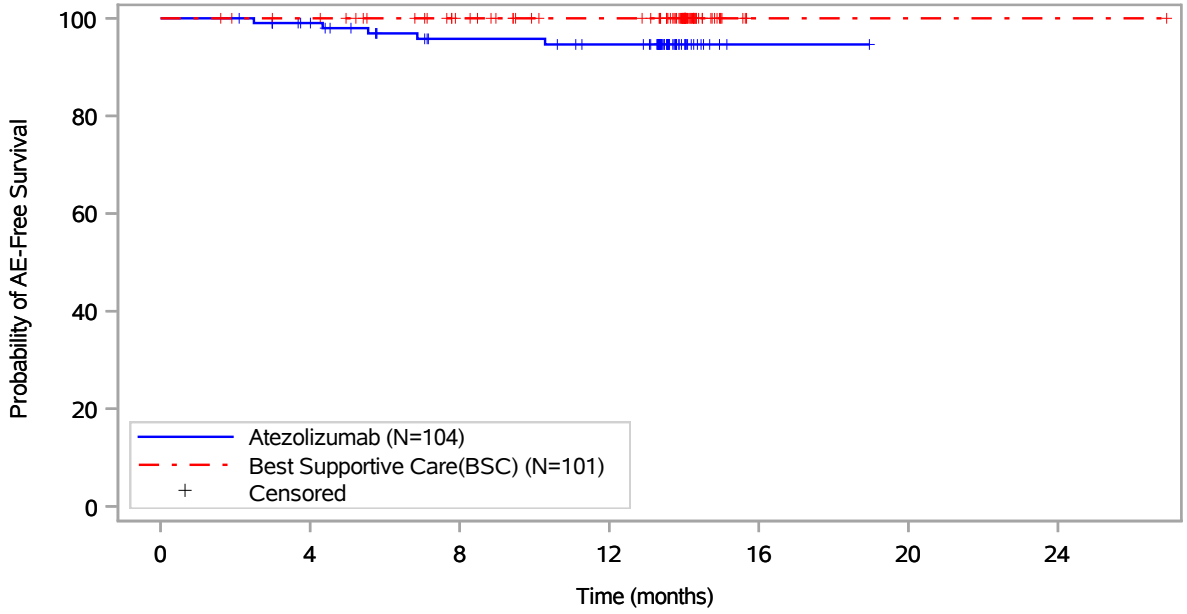


Patients at risk							
Atezolizumab (N=104)	104	91	77	70	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	97	82	72	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	17	20	89	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	95	95	95

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMHP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:05

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
STUDY: GO29527

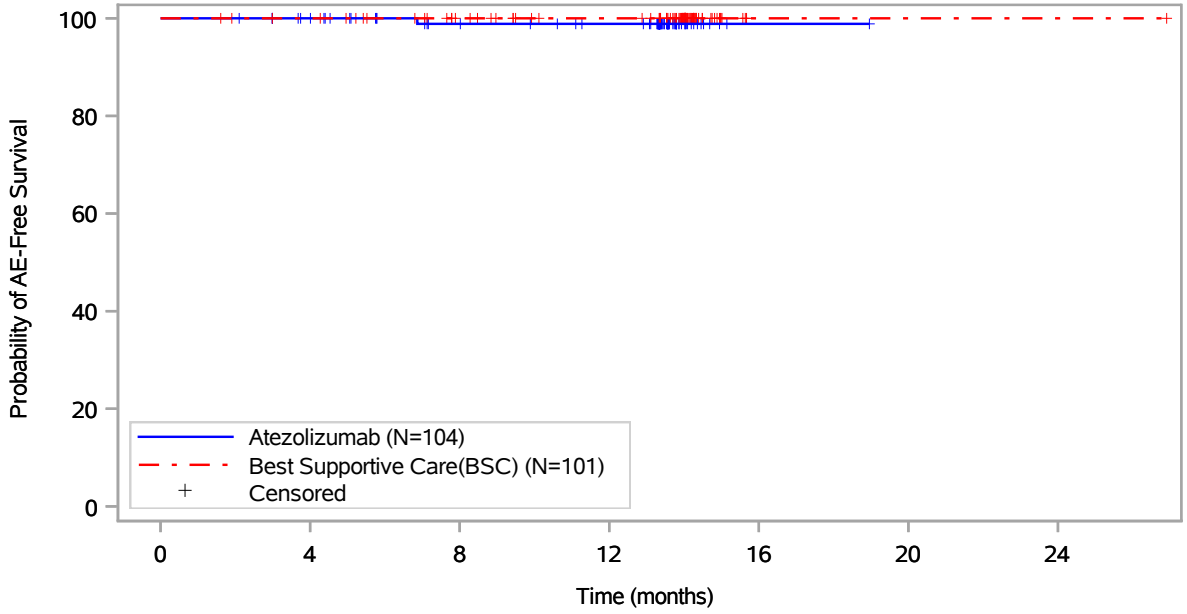


Patients at risk							
Atezolizumab (N=104)	104	96	83	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	17	20	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMHP35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:08

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
STUDY: GO29527

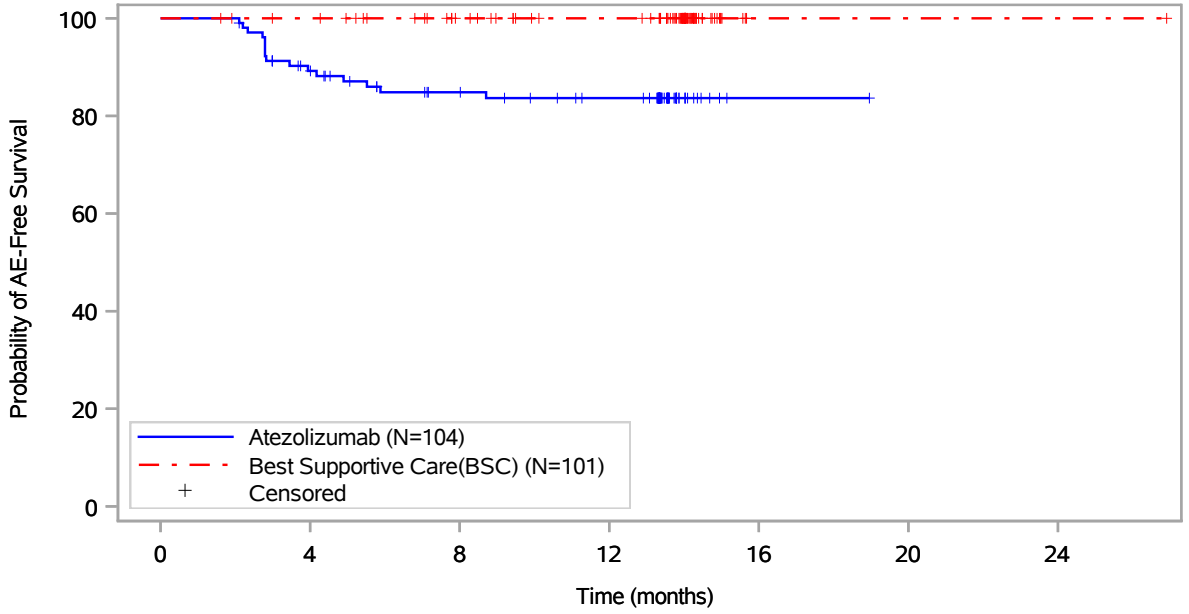


Patients at risk							
Atezolizumab (N=104)	104	97	84	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMHPS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:10

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
STUDY: GO29527

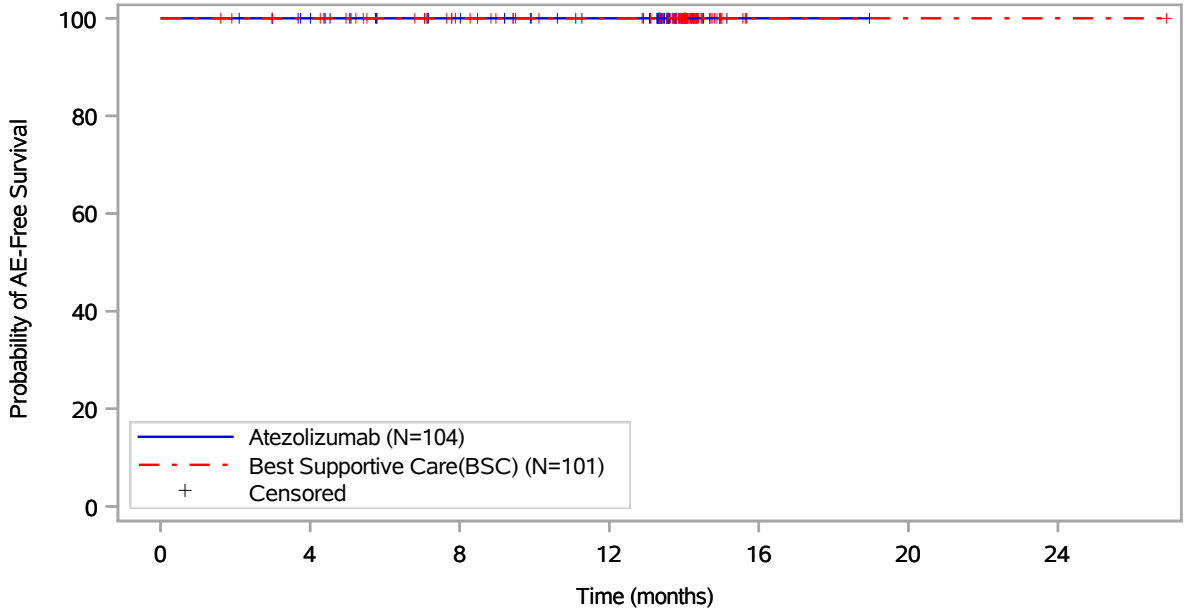


Patients at risk							
Atezolizumab (N=104)	104	86	72	65	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	17	23	87	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMLT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:12

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
STUDY: GO29527

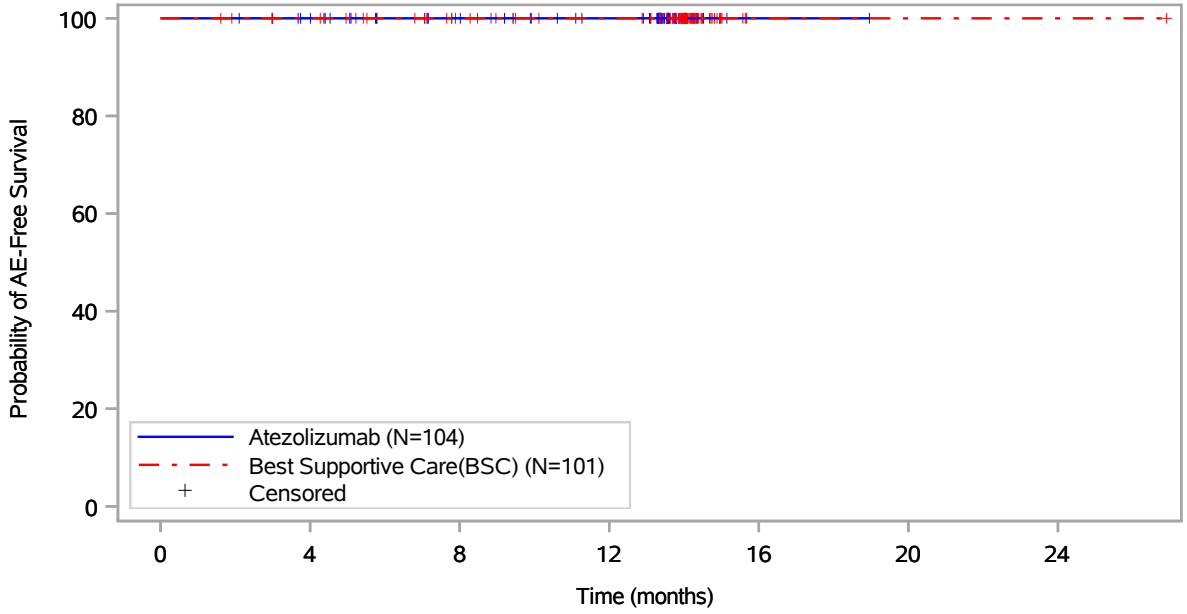


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMLT35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:15

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
STUDY: GO29527

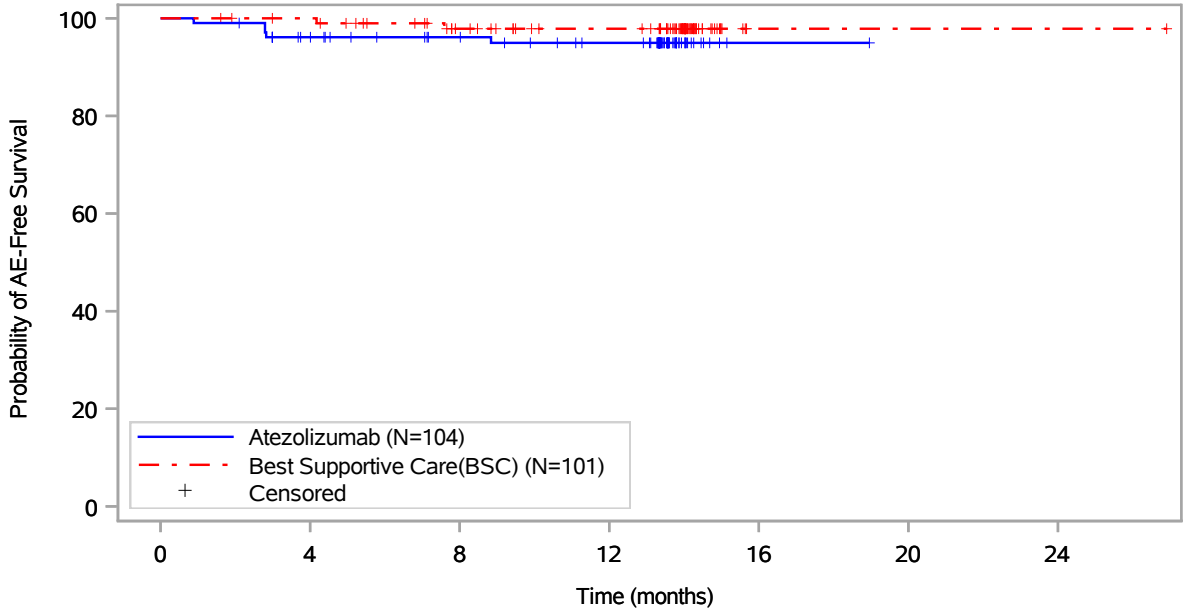


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMLTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:17

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
STUDY: GO29527

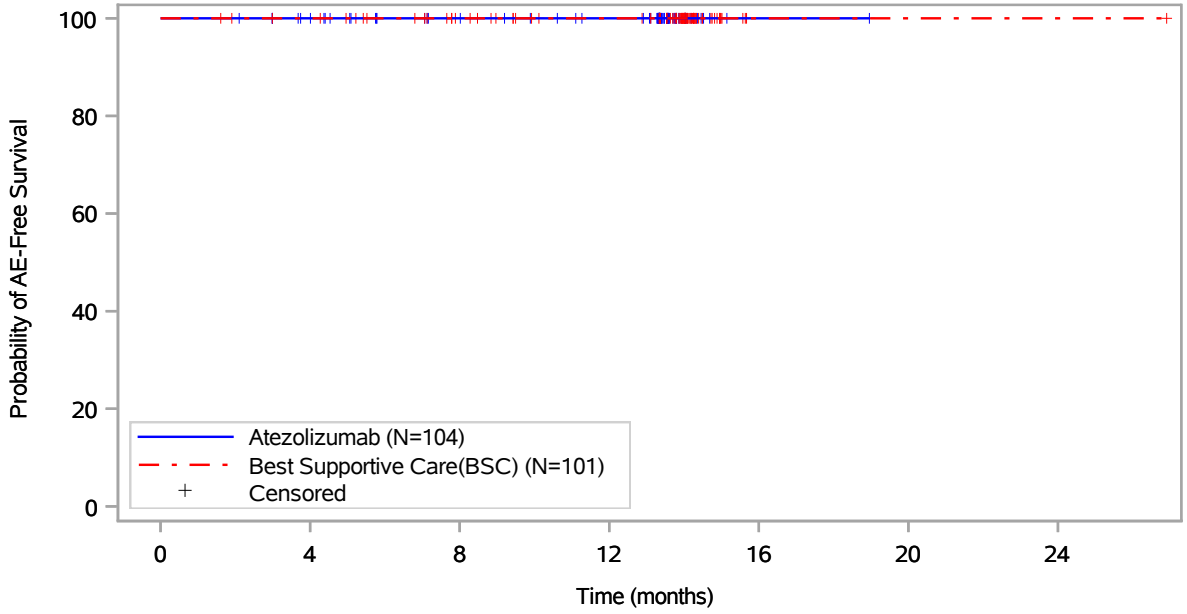


Patients at risk							
Atezolizumab (N=104)	104	93	84	77	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	84	75	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	16	22	98	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	98	98	98

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMHT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:20

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
STUDY: GO29527

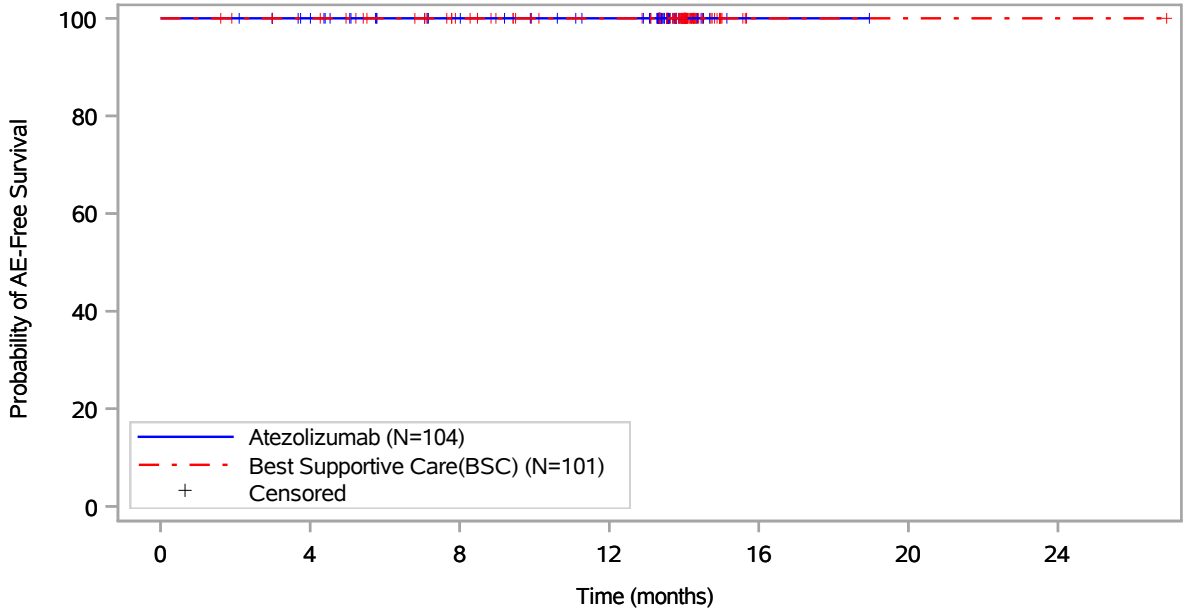


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMHT35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:23

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

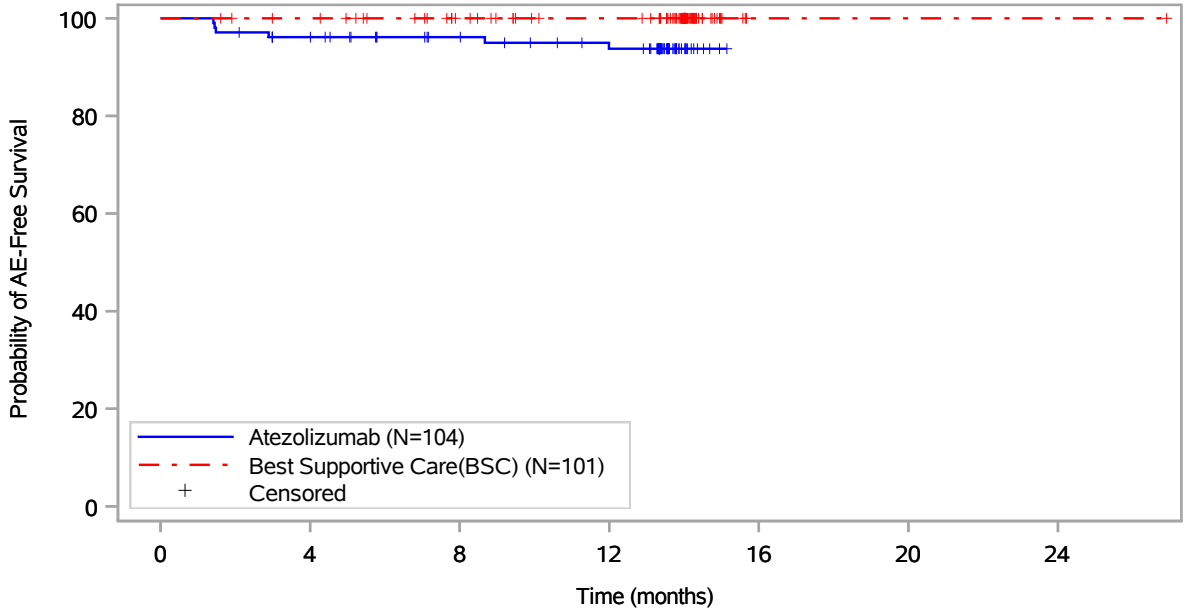


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMHTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:26

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
STUDY: GO29527

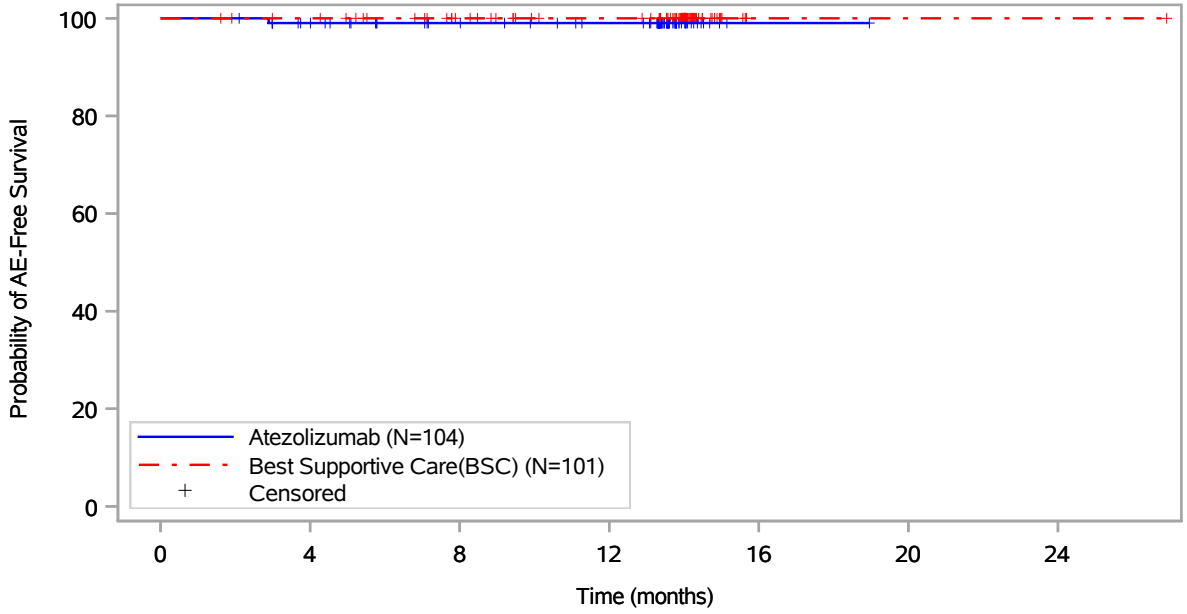


Patients at risk							
Atezolizumab (N=104)	104	95	84	77	NE	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	5	16	21	NE	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMPN_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:42

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
STUDY: GO29527

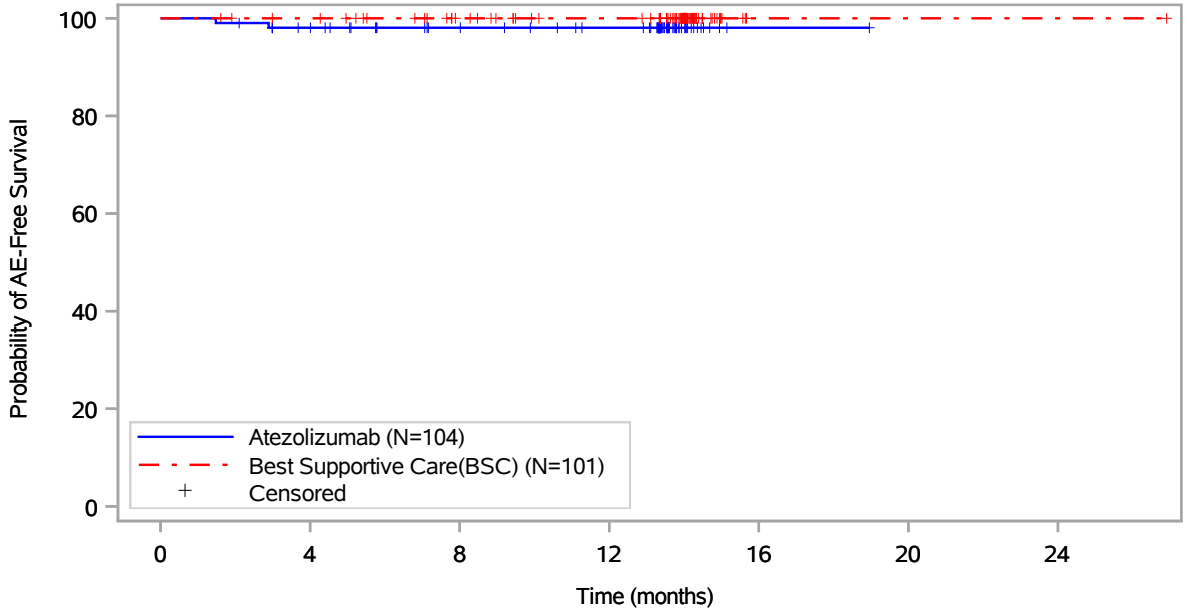


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMPN35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:48

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
STUDY: GO29527

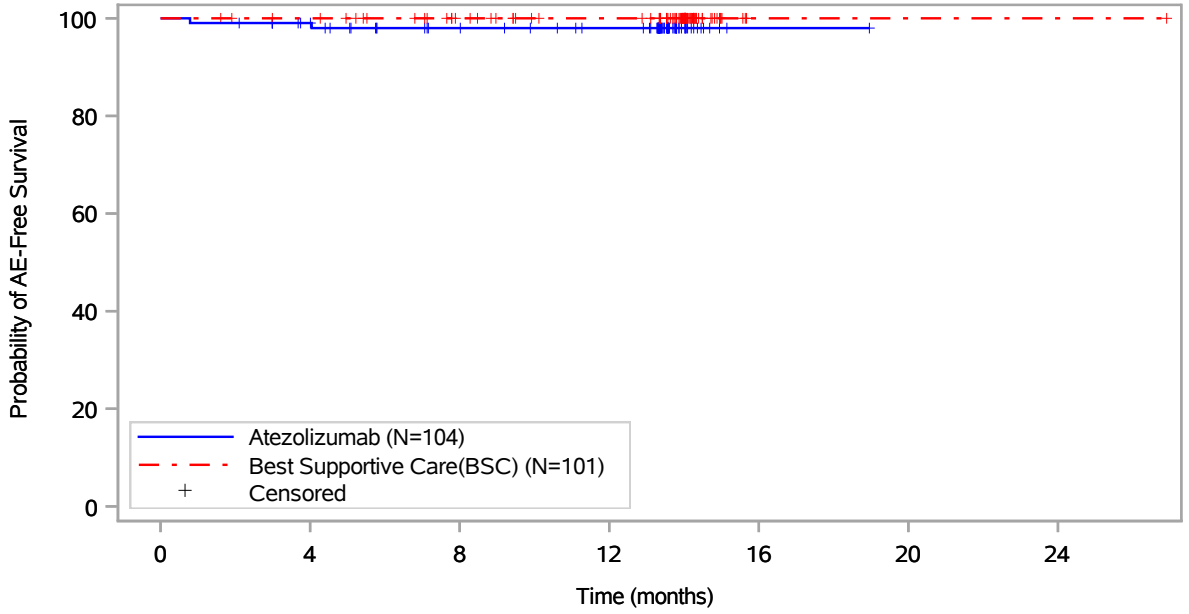


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMPNS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:54

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
STUDY: GO29527

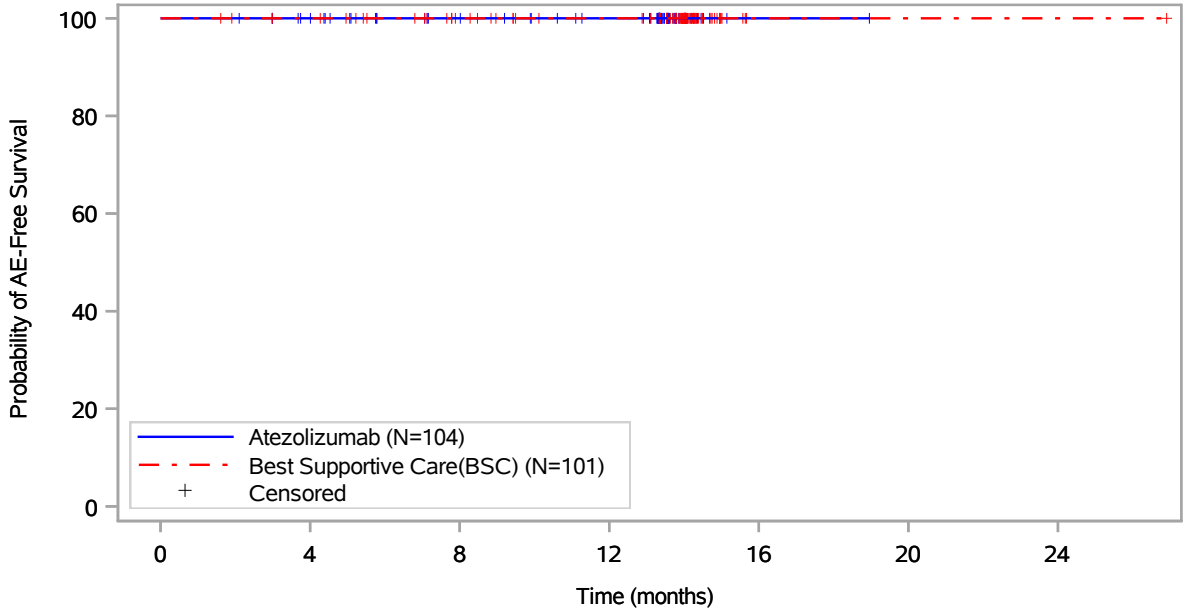


Patients at risk							
Atezolizumab (N=104)	104	96	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMSR_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:15

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
STUDY: GO29527

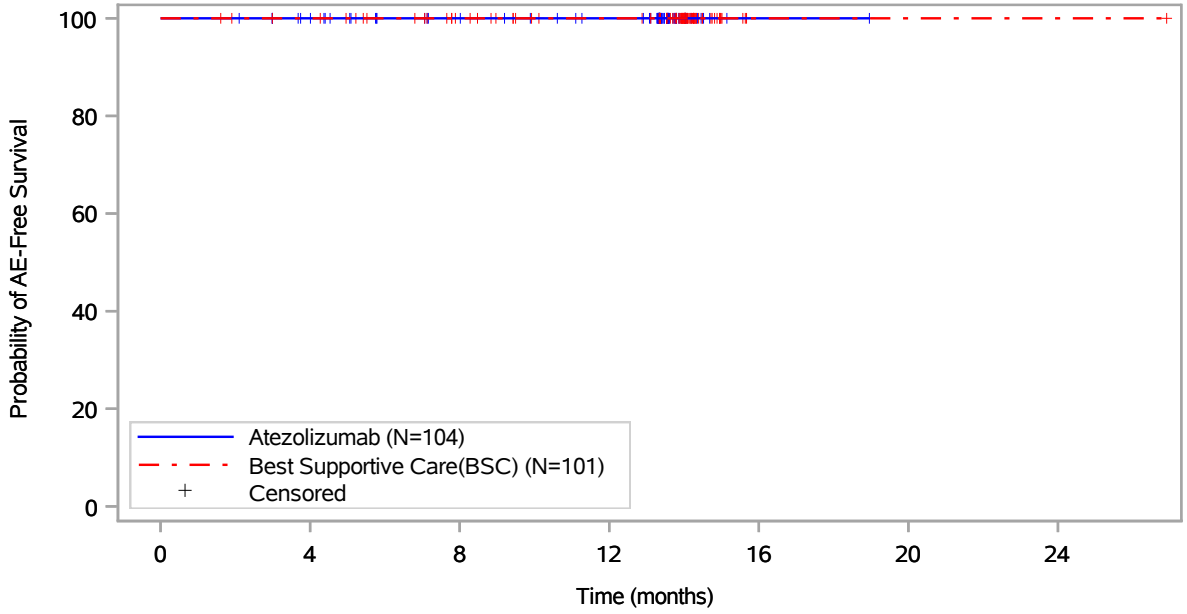


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMSR35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:19

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
STUDY: GO29527

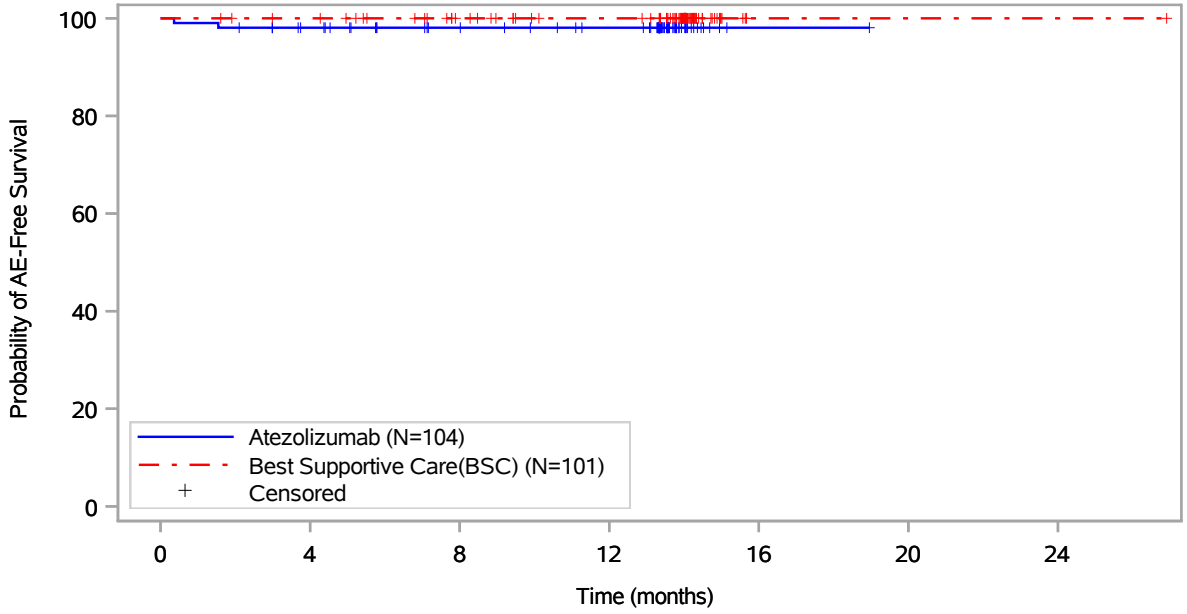


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMSRS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:22

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
STUDY: GO29527

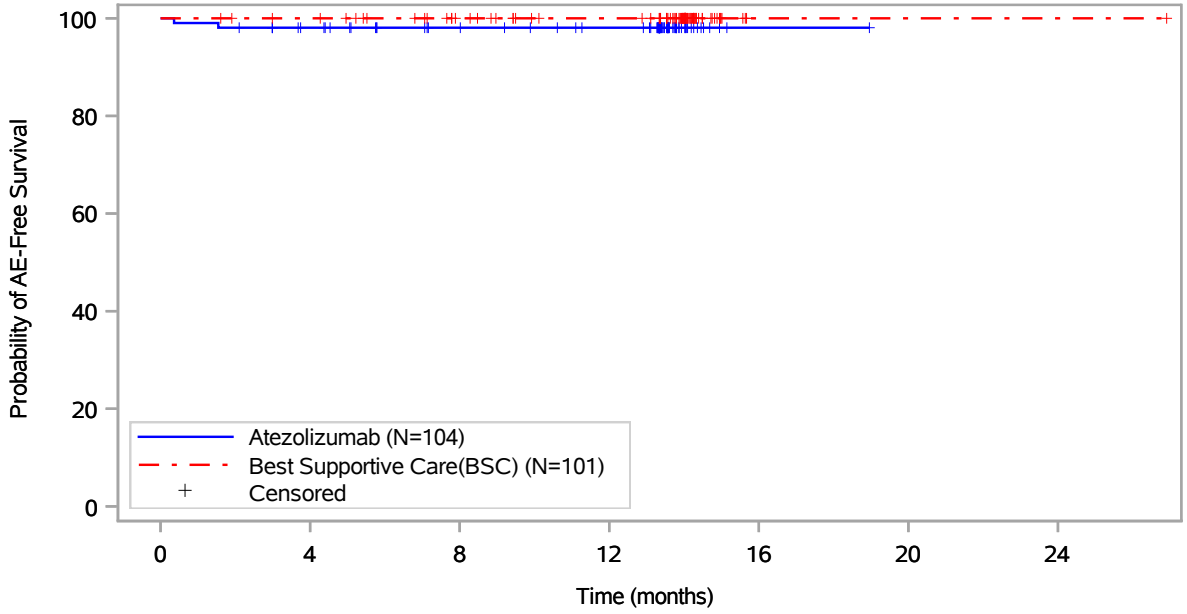


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMME_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 0:48

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
STUDY: GO29527

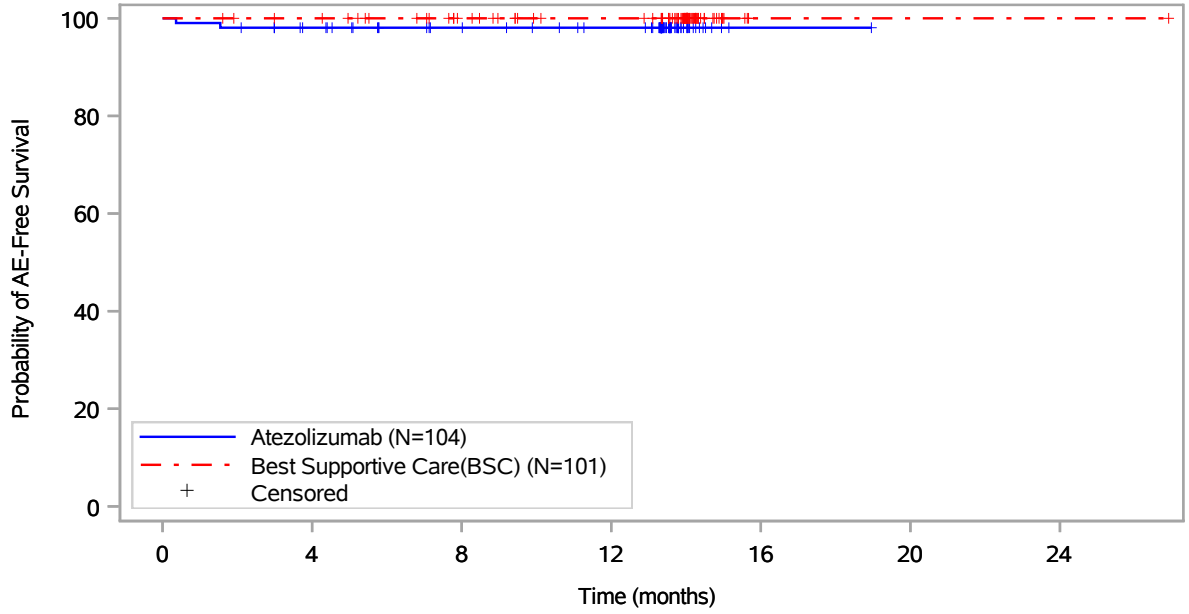


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMME35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 0:50

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
STUDY: GO29527

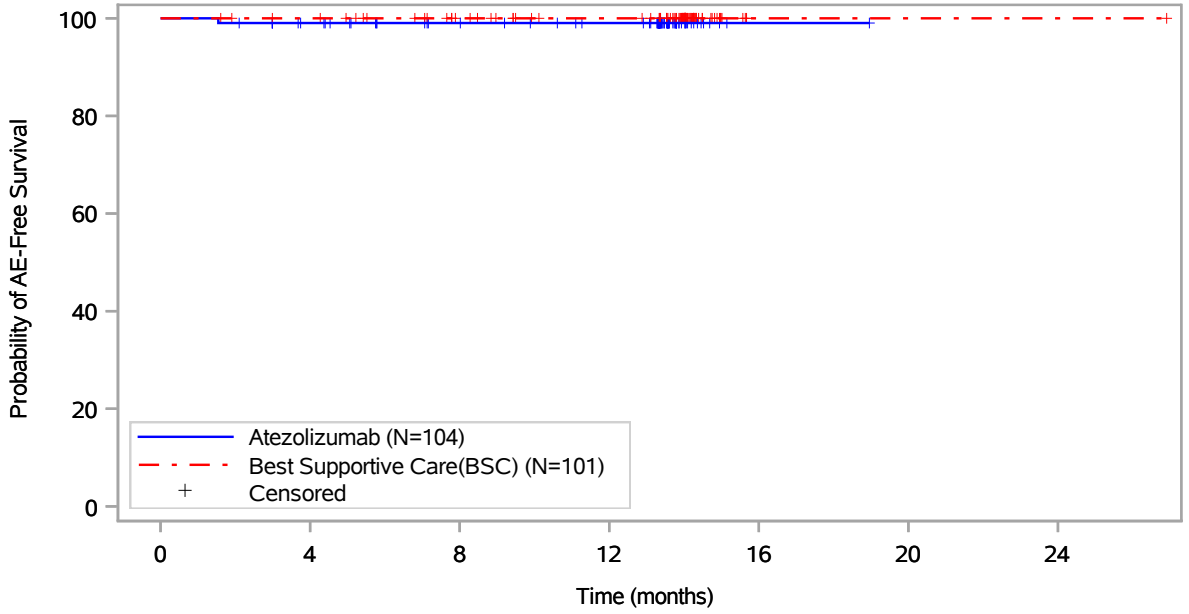


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	17	23	101	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMMES_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 0:53

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
STUDY: GO29527

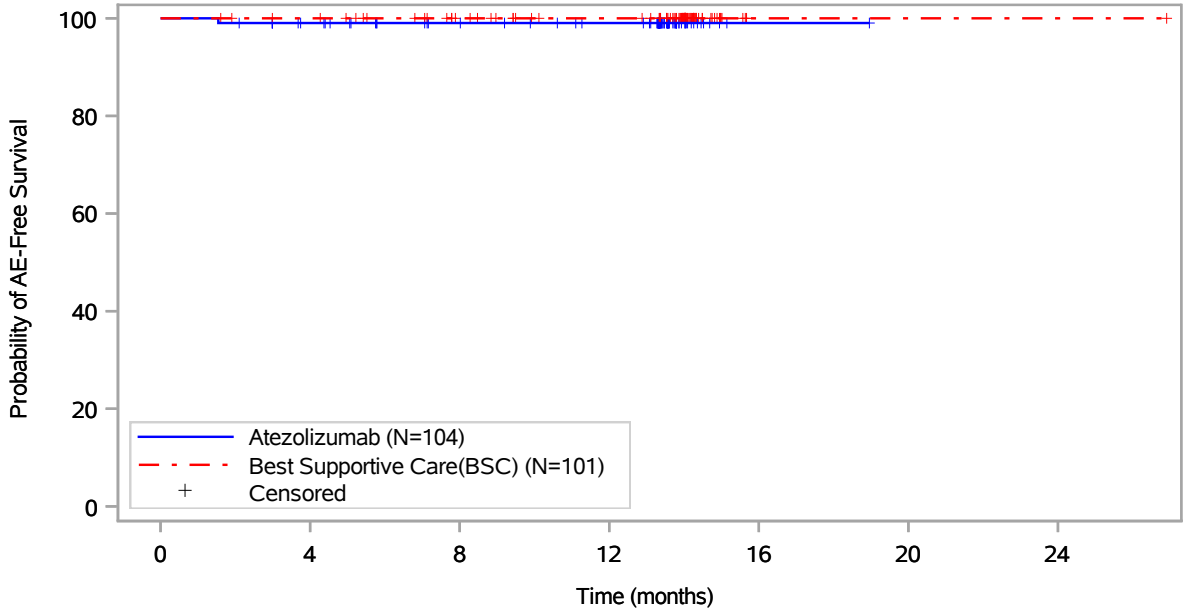


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMMI_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:06

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
STUDY: GO29527

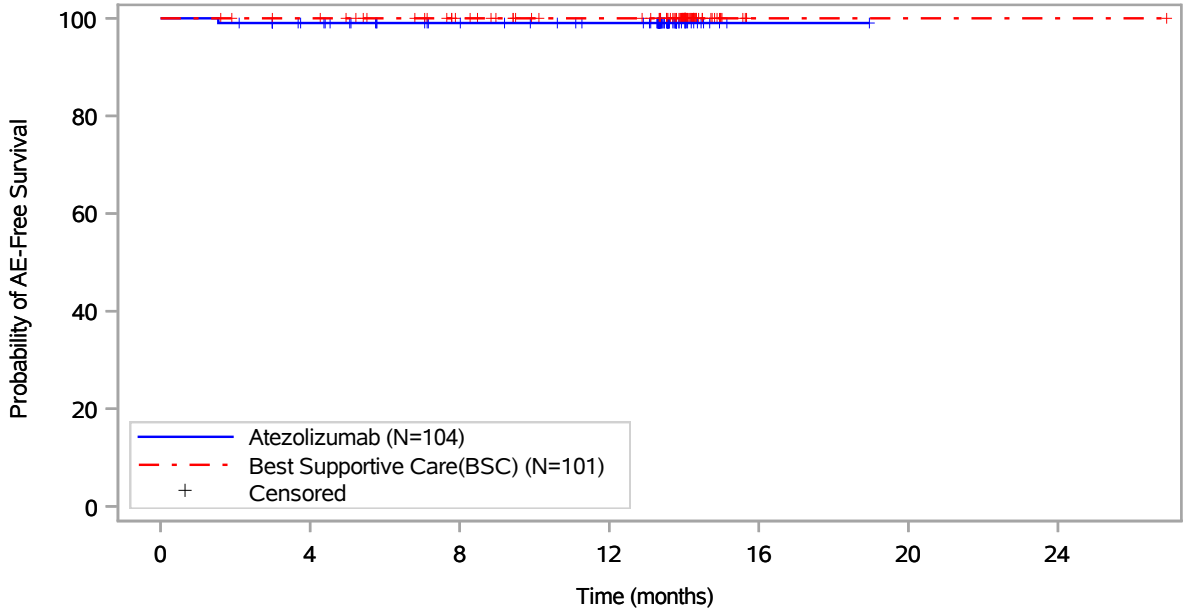


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMMI35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:08

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
STUDY: GO29527

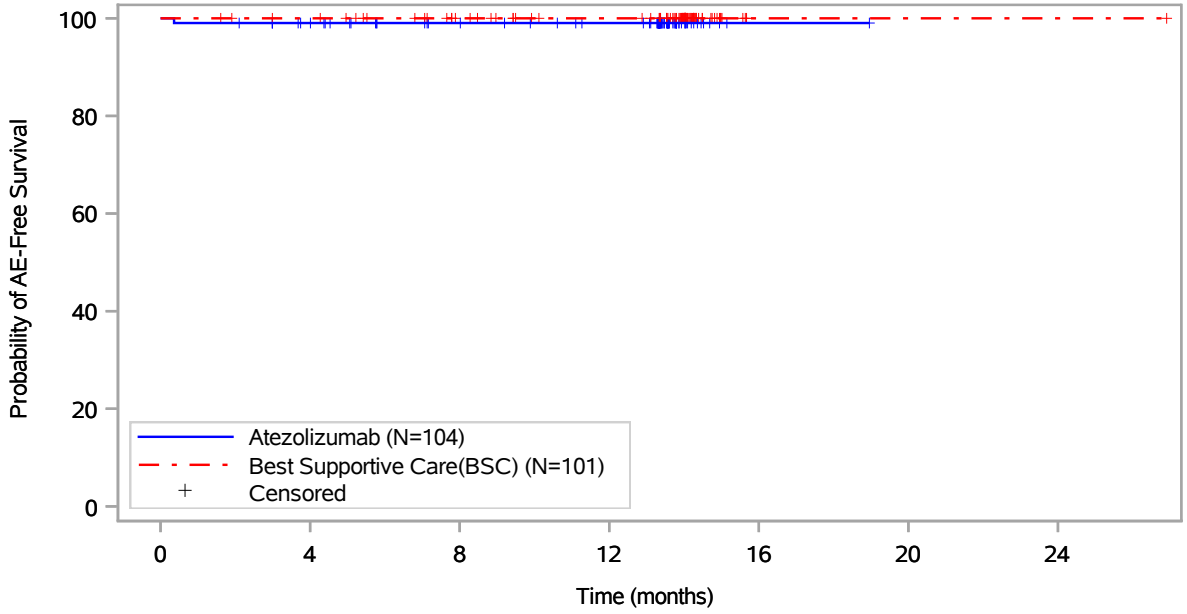


Patients at risk							
Atezolizumab (N=104)	104	96	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMMIS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:12

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
STUDY: GO29527

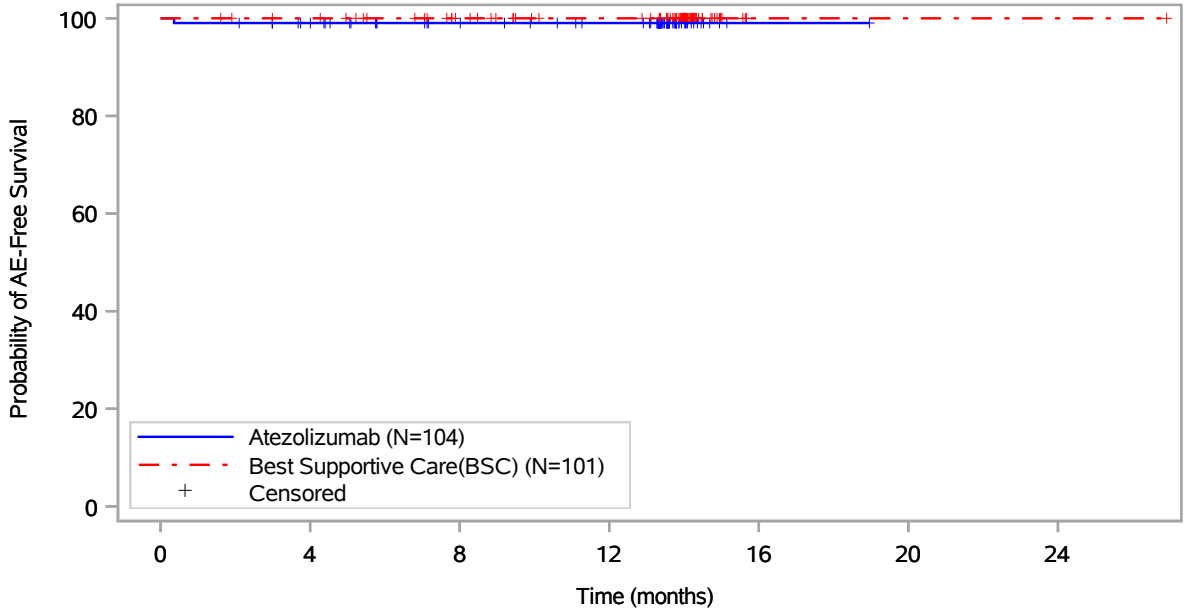


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMEP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:14

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
STUDY: GO29527

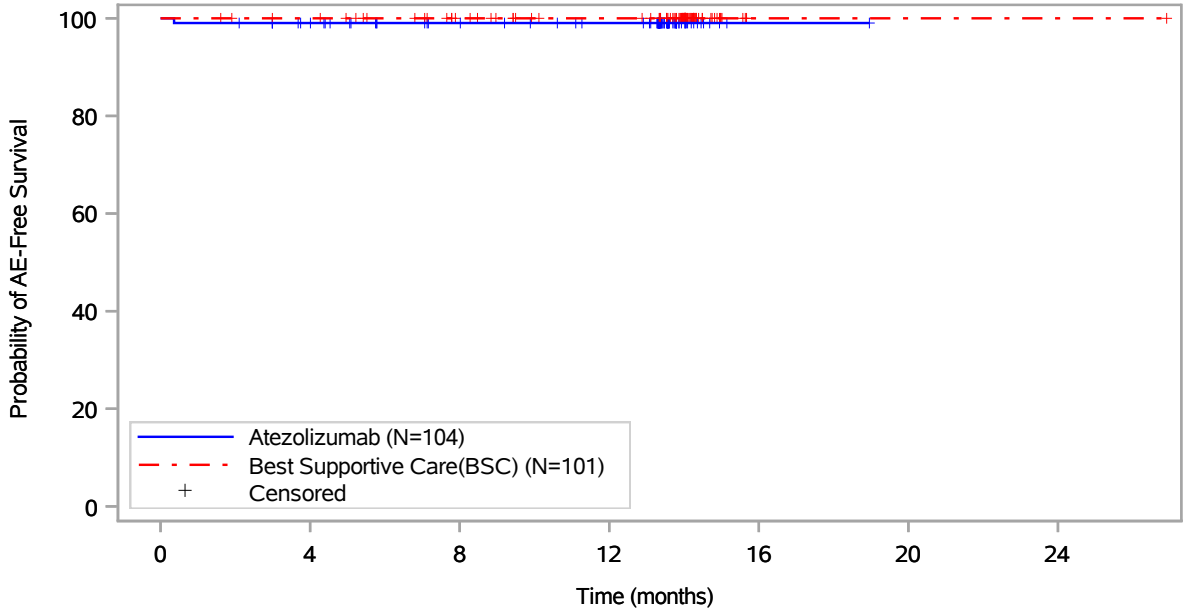


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMEP35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:17

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

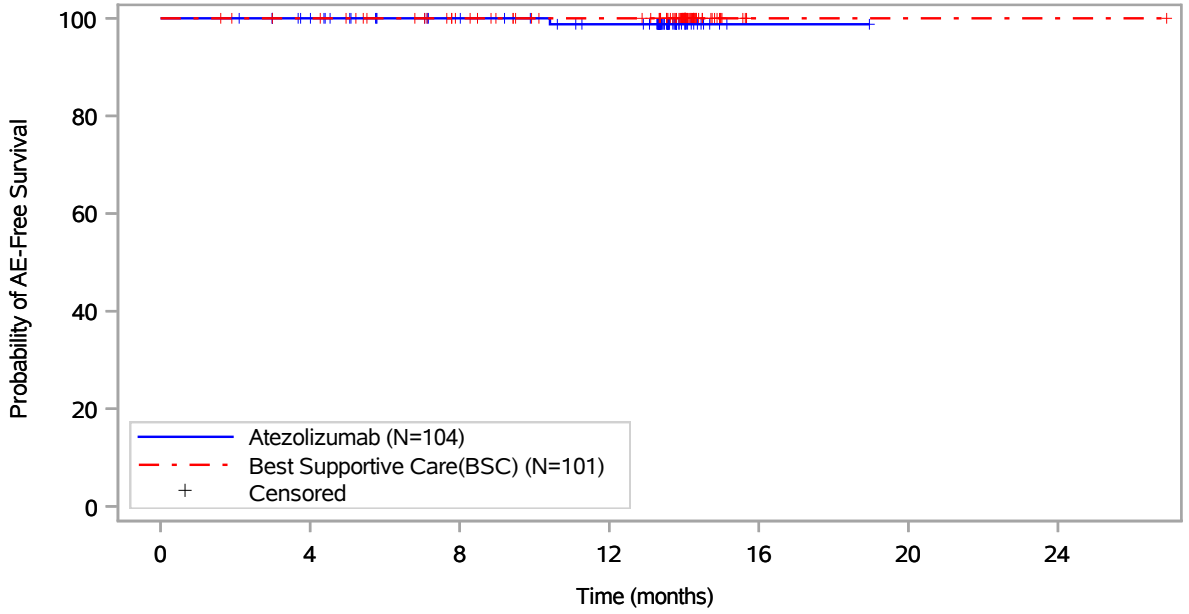


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	6	18	24	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMEPS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:19

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
STUDY: GO29527

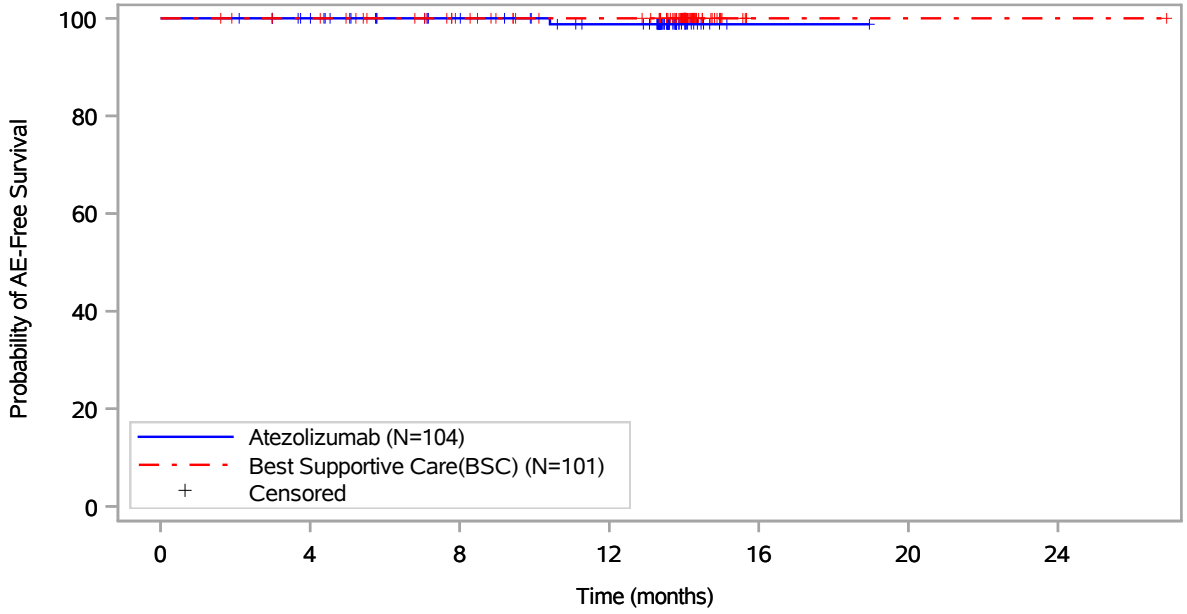


Patients at risk							
Atezolizumab (N=104)	104	97	85	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMCL_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:59

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
STUDY: GO29527

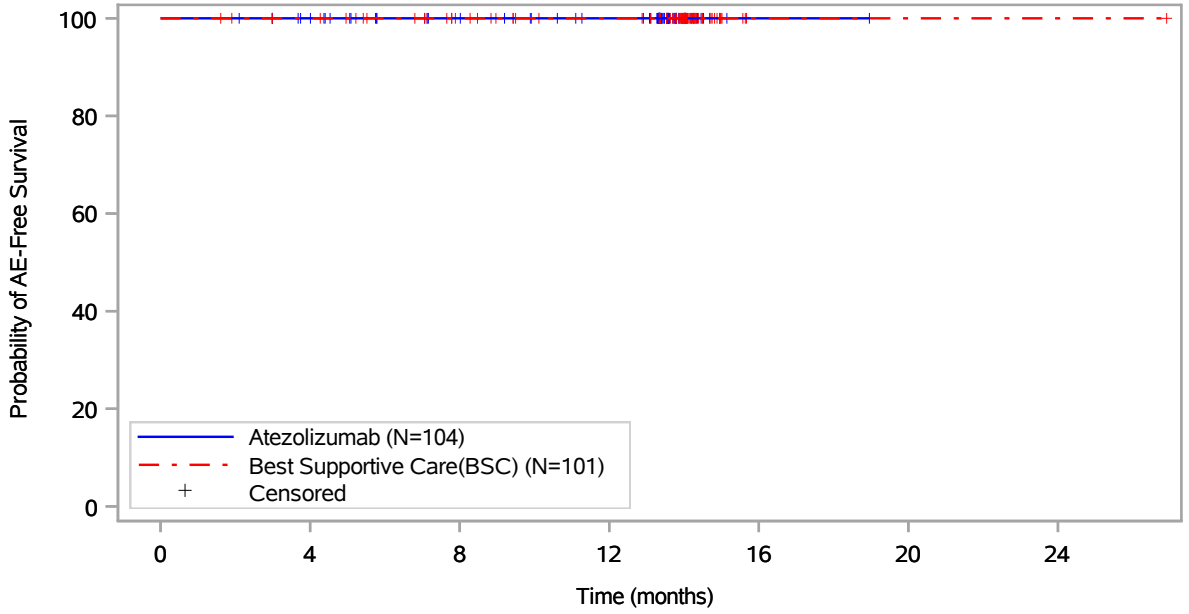


Patients at risk							
Atezolizumab (N=104)	104	97	85	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..CE_DFS_FA/prod/output/g_km_TTIMCL35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:03

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
STUDY: GO29527

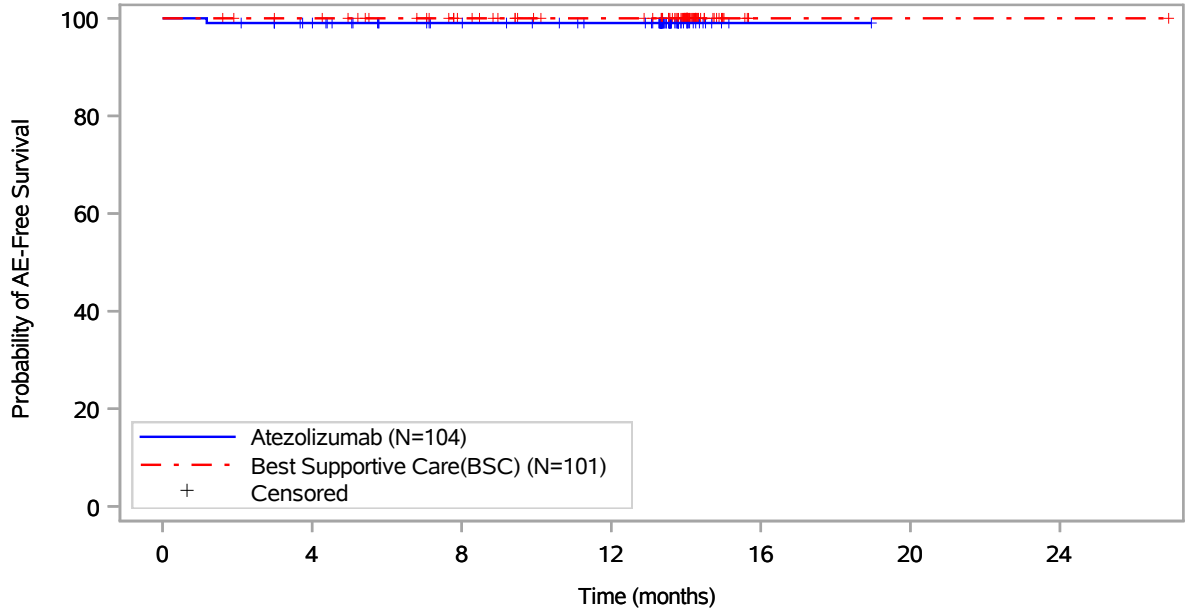


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMCLS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:07

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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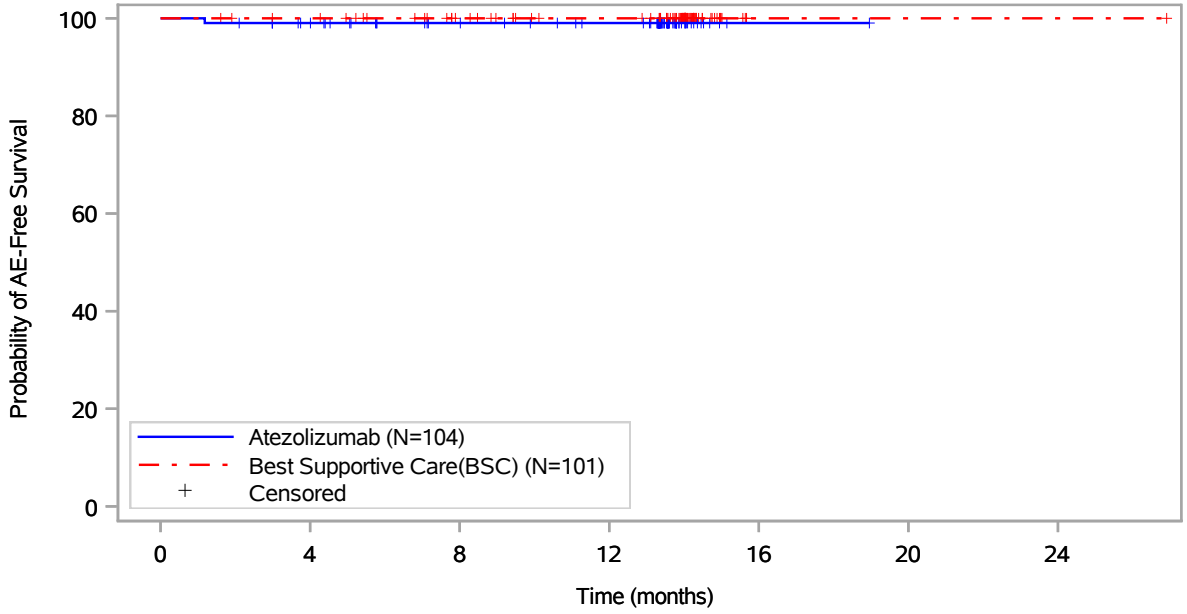
01MAY2024 2:10

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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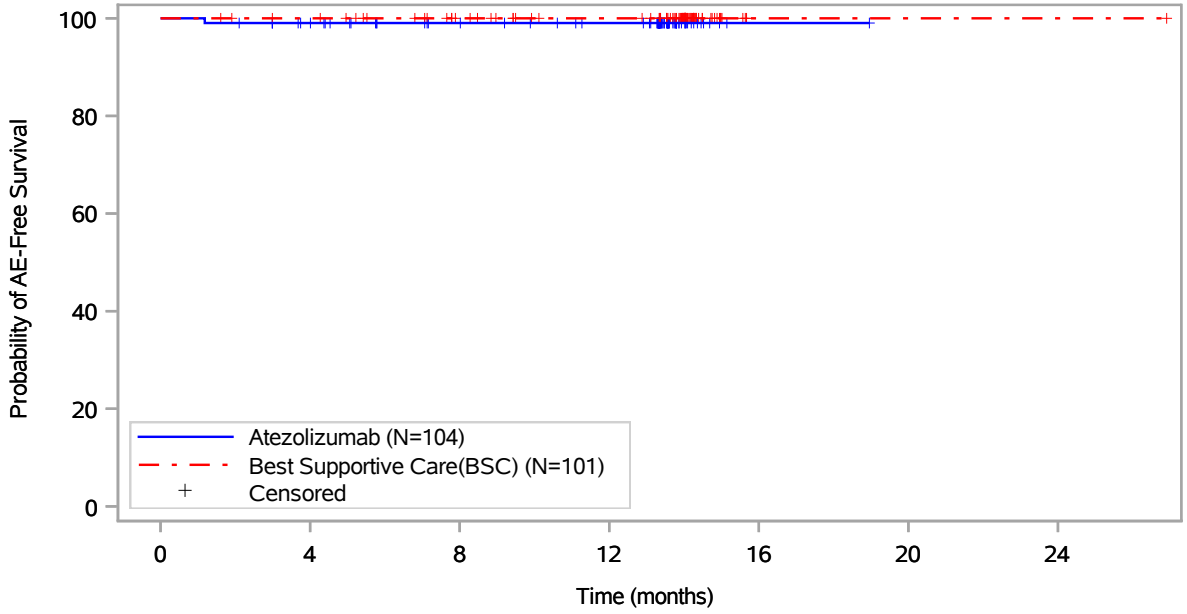
01MAY2024 2:14

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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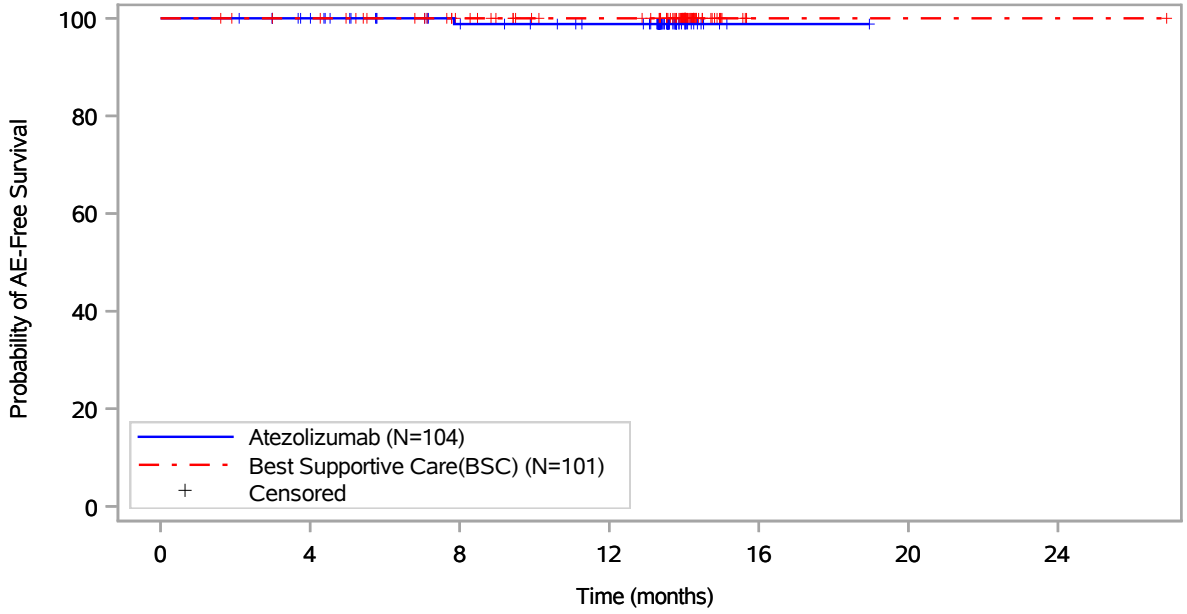
01MAY2024 2:16

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

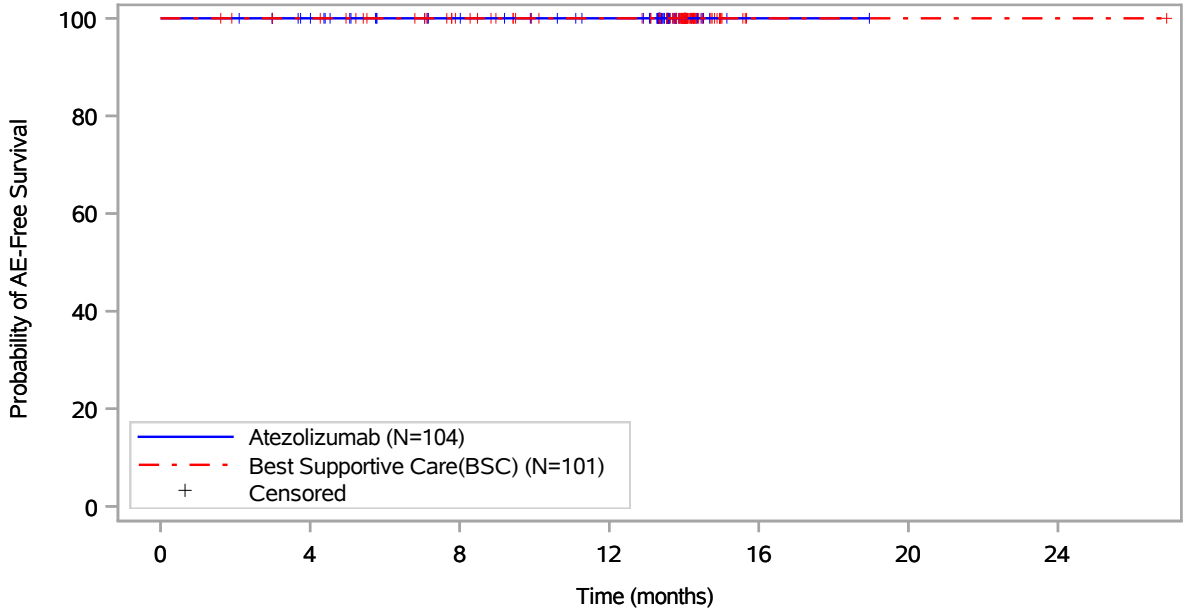


Patients at risk							
Atezolizumab (N=104)	104	97	84	78	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	102	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMOT_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:22

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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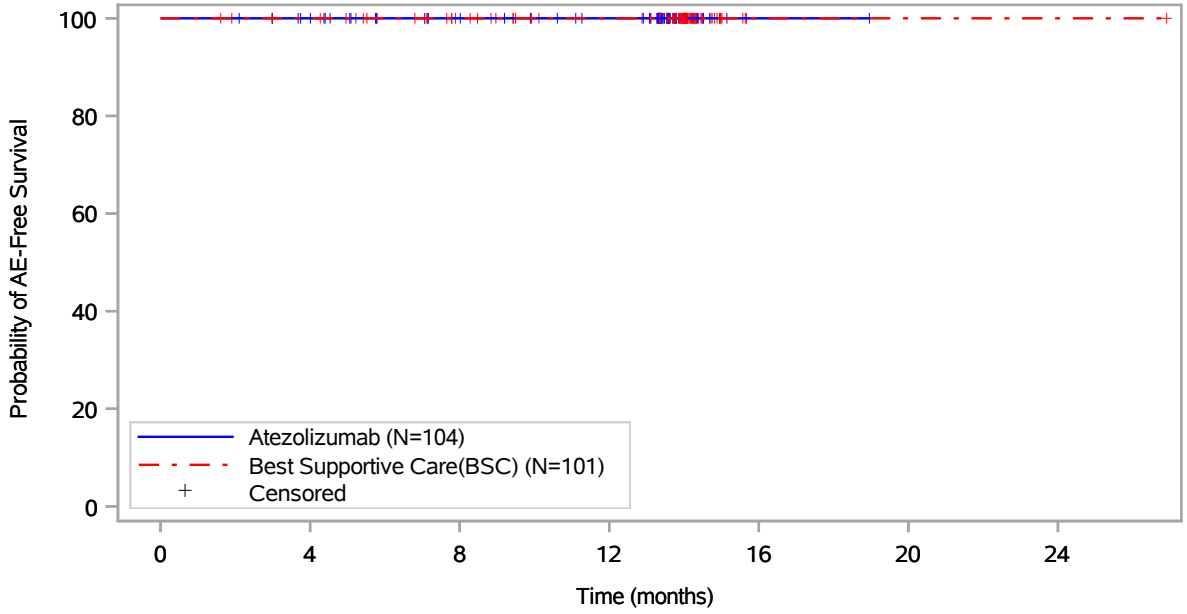
01MAY2024 1:25

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

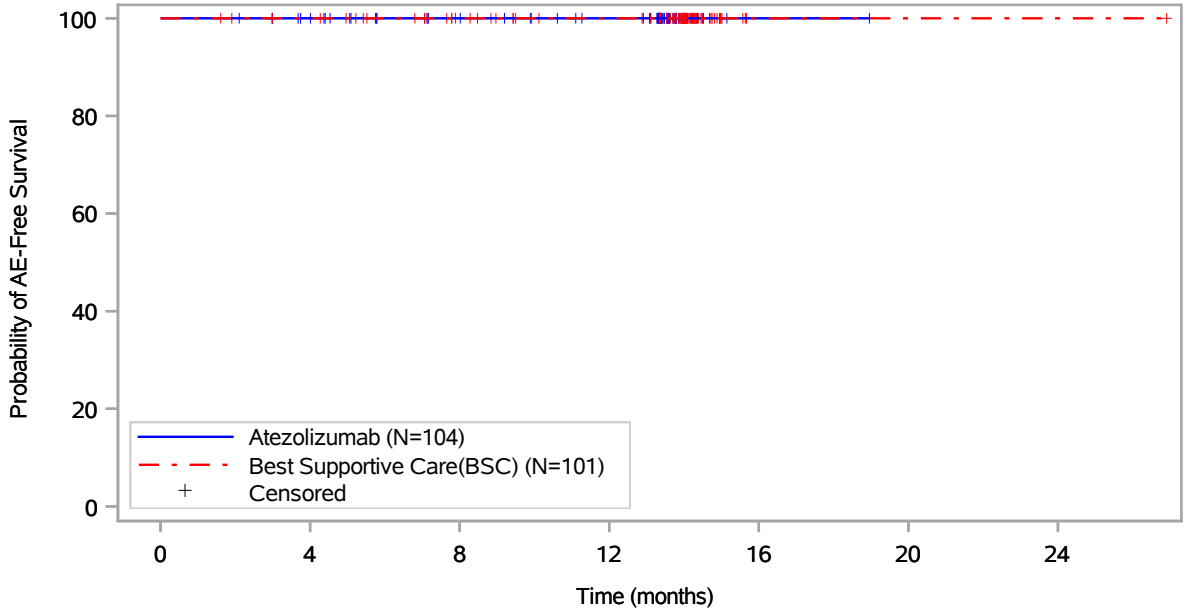


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..ACE_DFS_FA/prod/output/g_km_TTIMOTS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:27

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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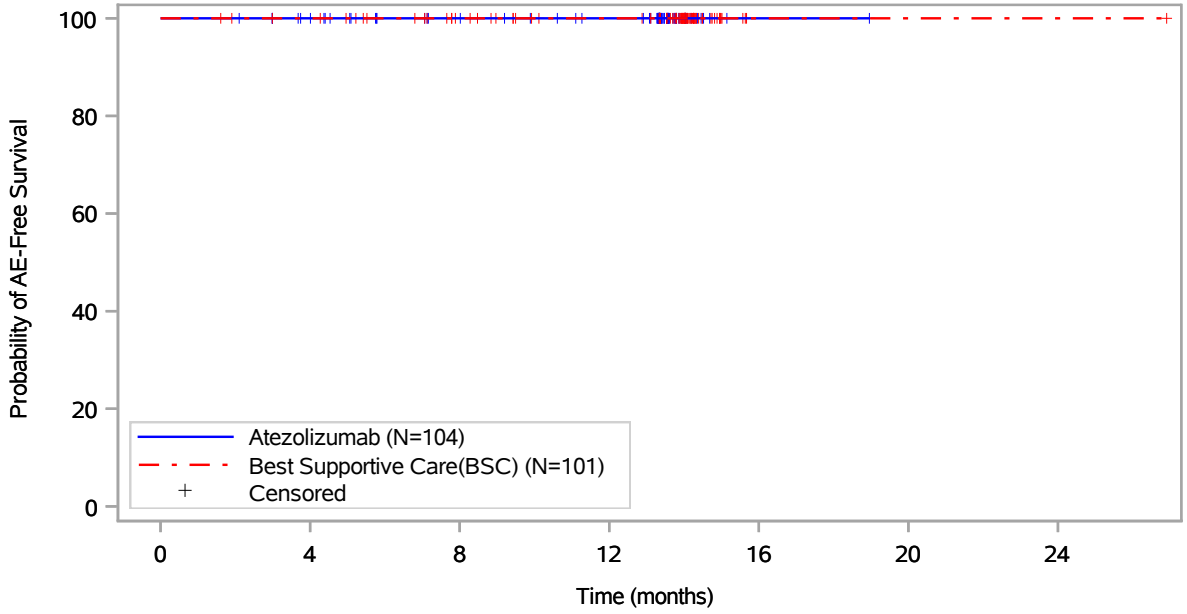
01MAY2024 2:24

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

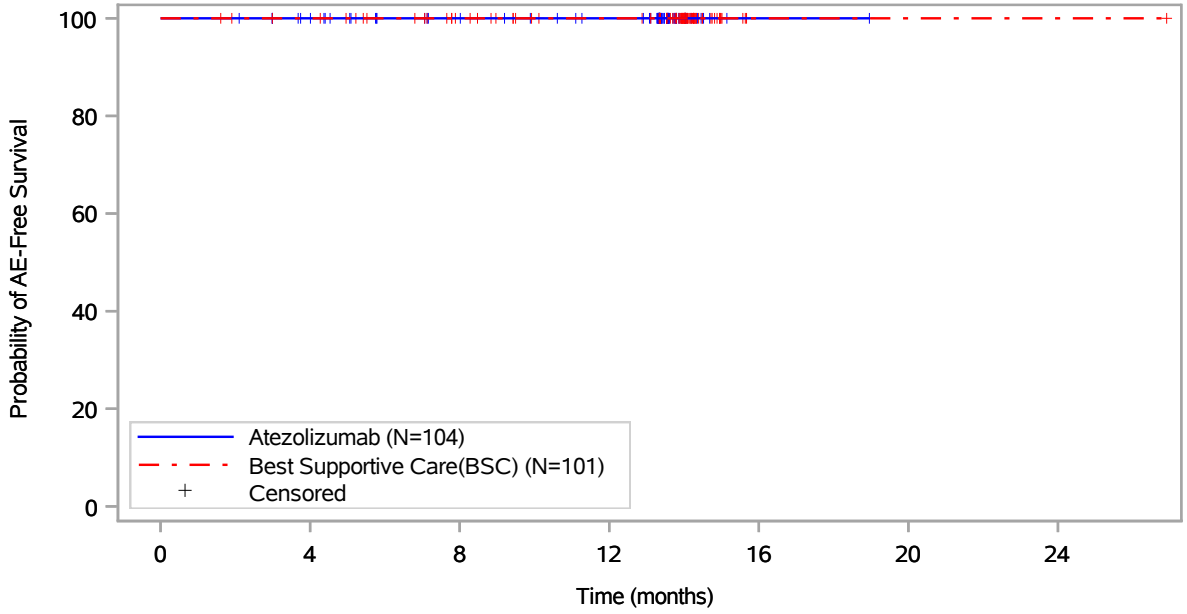


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMAI_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:28

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
STUDY: GO29527

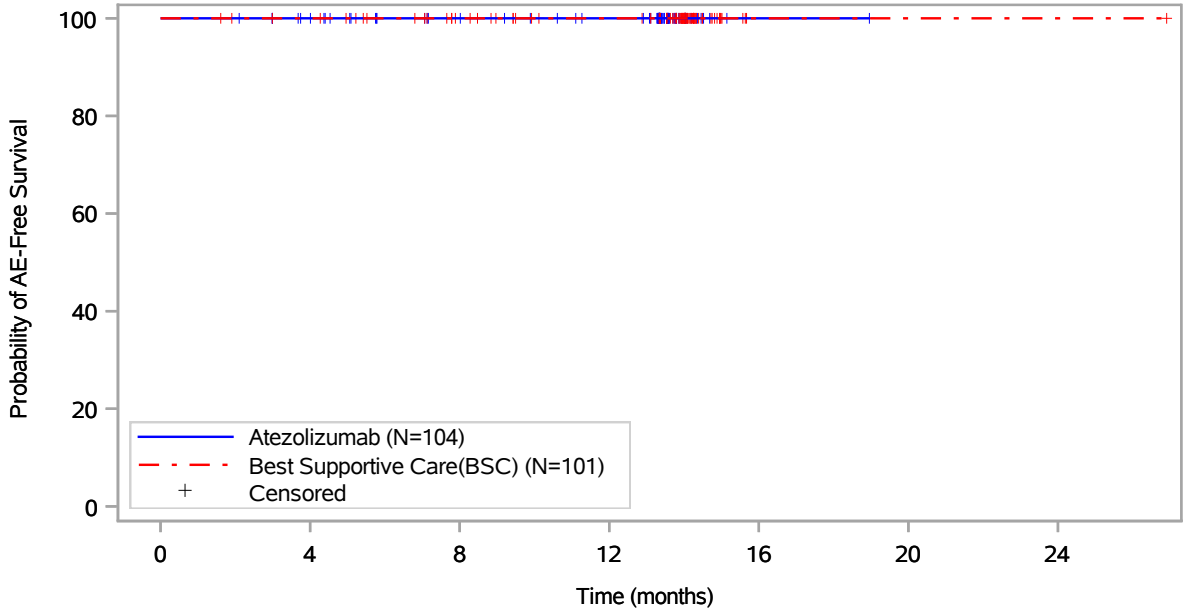


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMDM_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:10

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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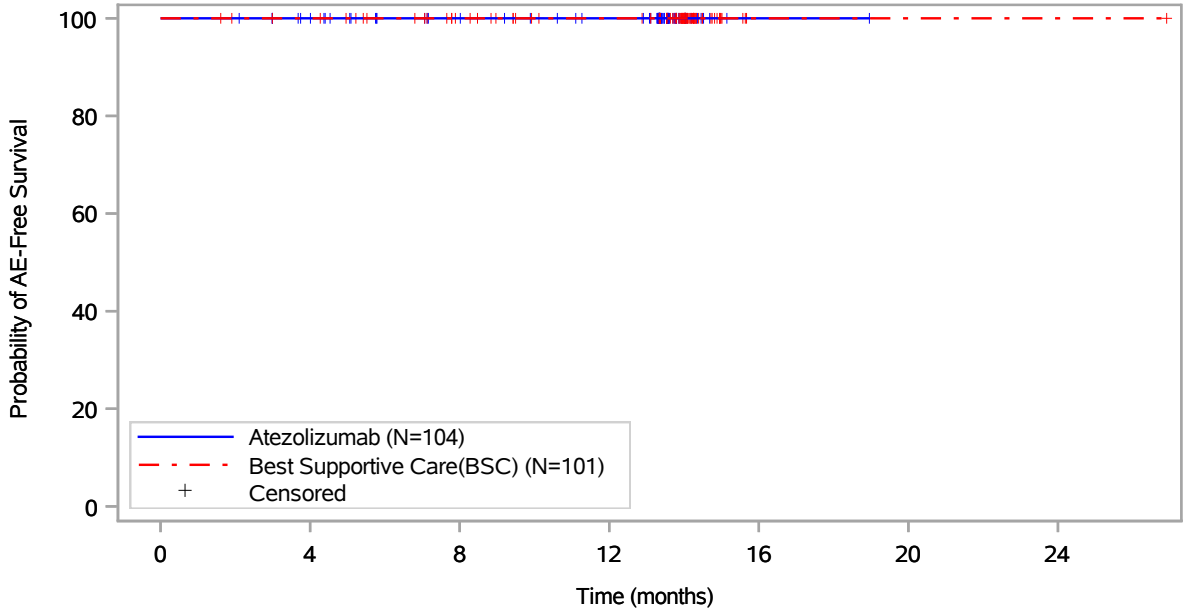
01MAY2024 1:50

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
STUDY: GO29527

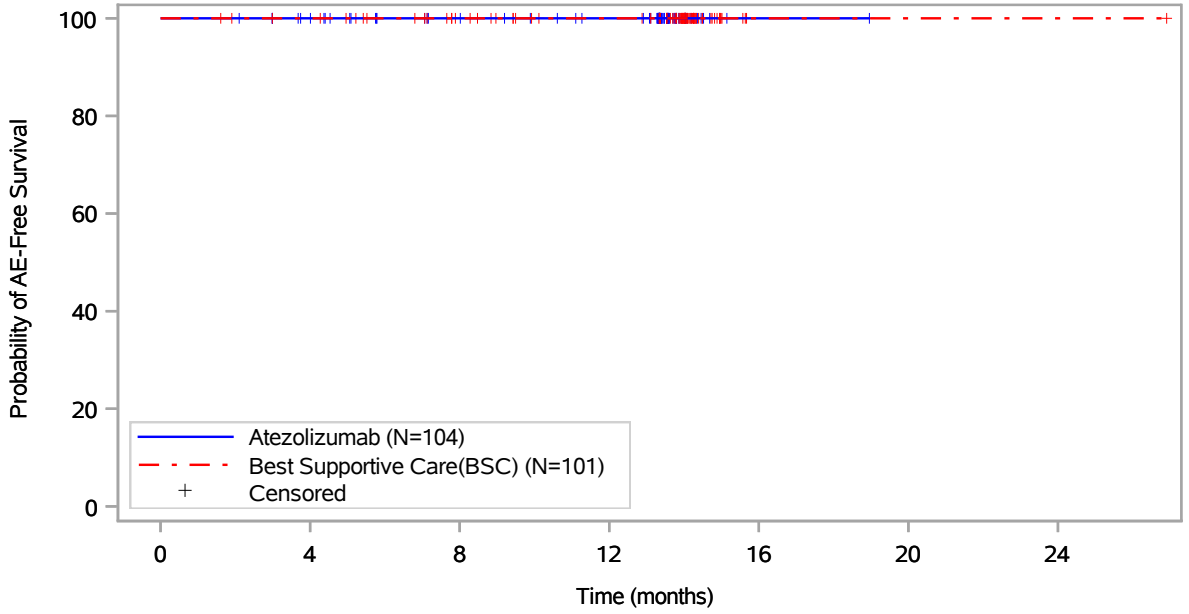


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMMG_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:19

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
STUDY: GO29527

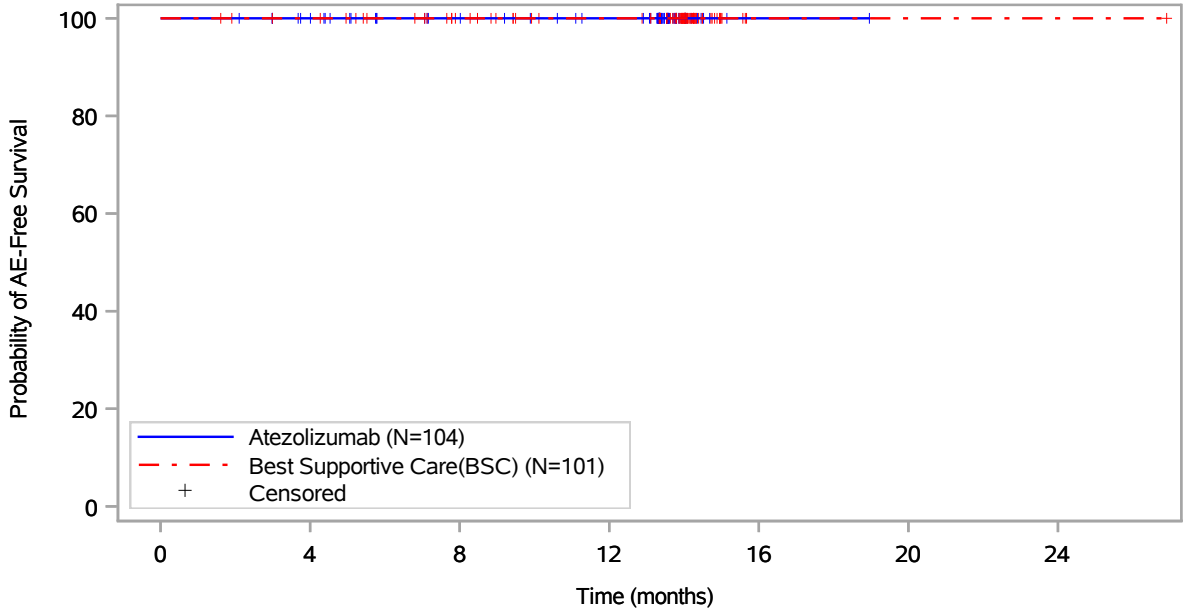


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMMC_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 2:07

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
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
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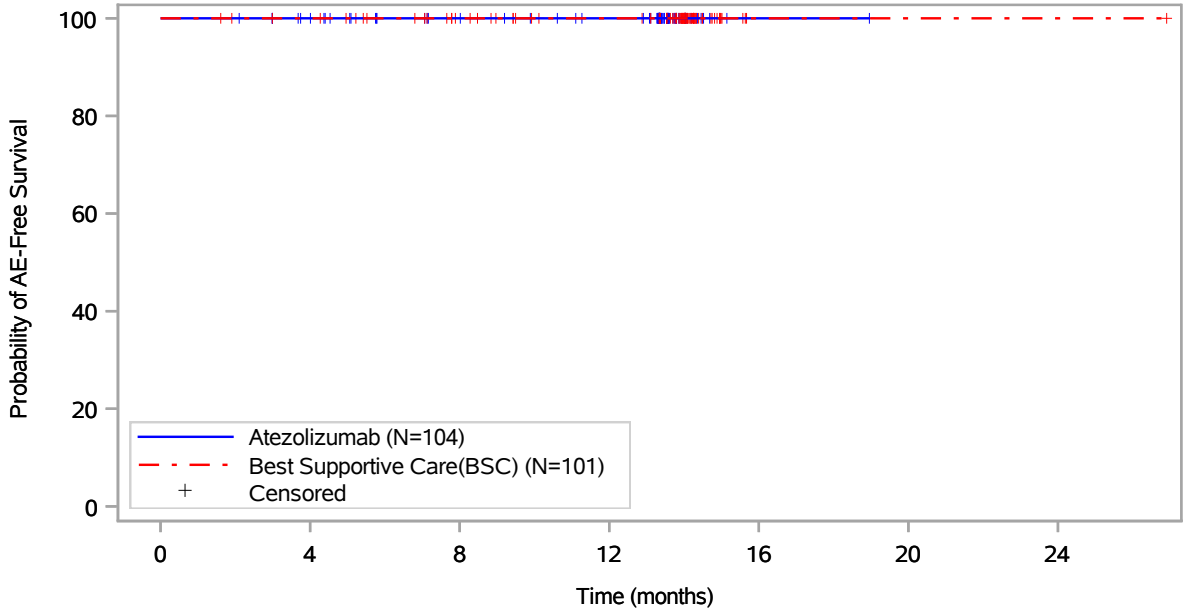
01MAY2024 1:17

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
STUDY: GO29527

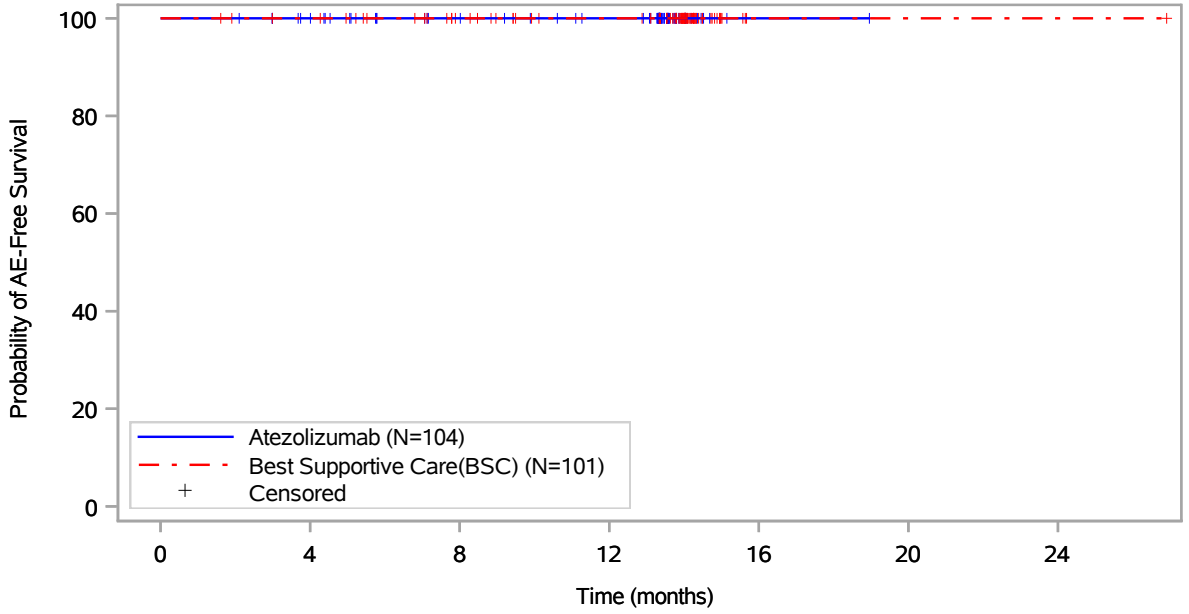


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMNP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:33

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
STUDY: GO29527

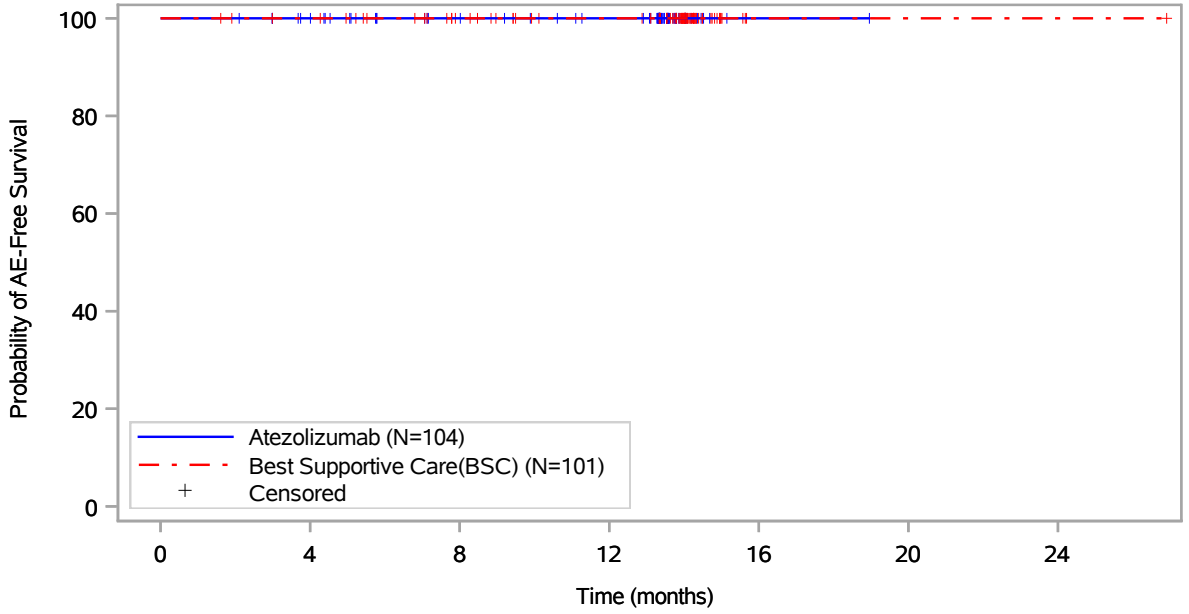


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMPC_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:02

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
STUDY: GO29527

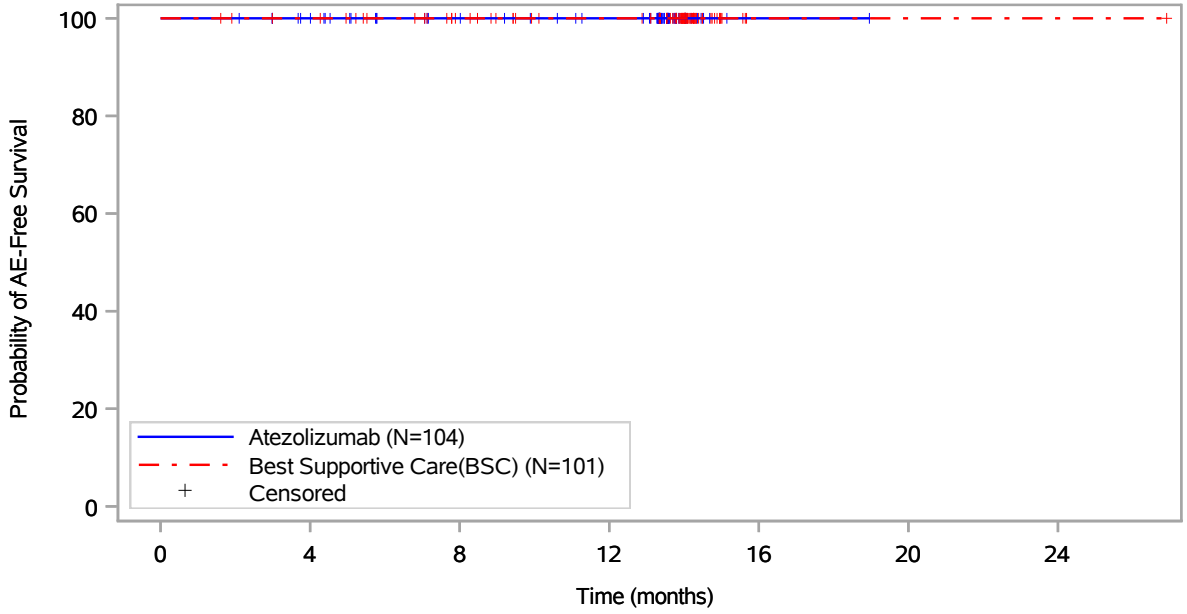


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTIMVS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:33

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
STUDY: GO29527

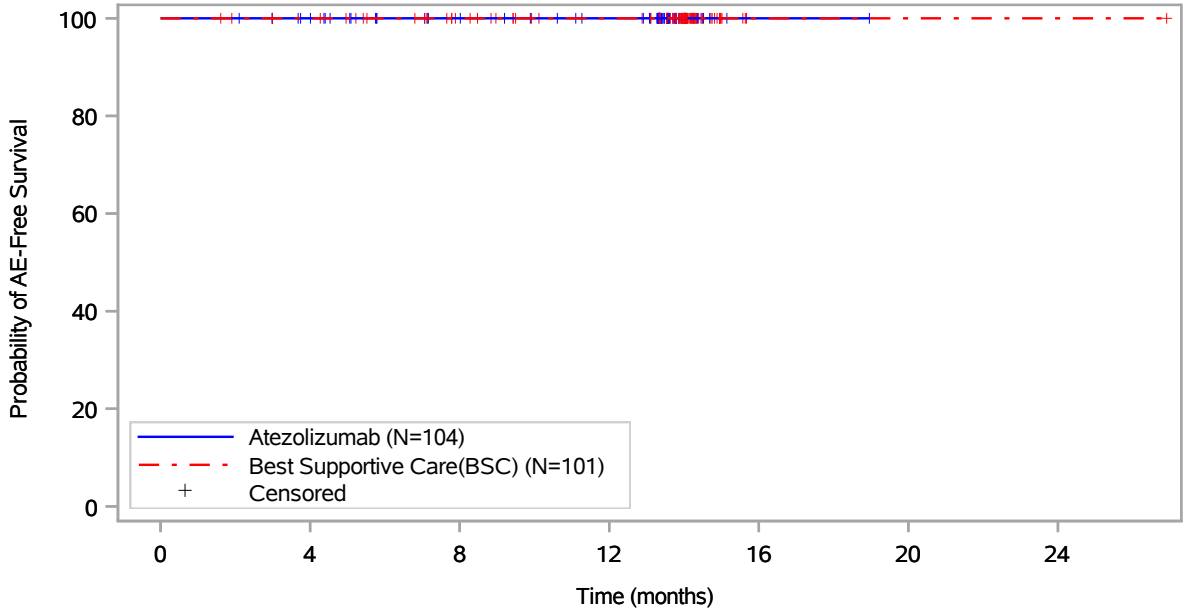


Patients at risk							
Atezolizumab (N=104)	104	97	85	79	1	NE	NE
Best Supportive Care(BSC) (N=101)	101	98	86	77	1	1	1
Patients censored							
Atezolizumab (N=104)	0	7	19	25	103	NE	NE
Best Supportive Care(BSC) (N=101)	0	3	15	24	100	100	100

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..s/ACE_DFS_FA/prod/output/g_km_TTIRR_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 0:55

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Time to First Rhabdomyolysis
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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ../ACE_DFS_FA/prod/output/g_km_TTRHAB_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
01MAY2024 1:25

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

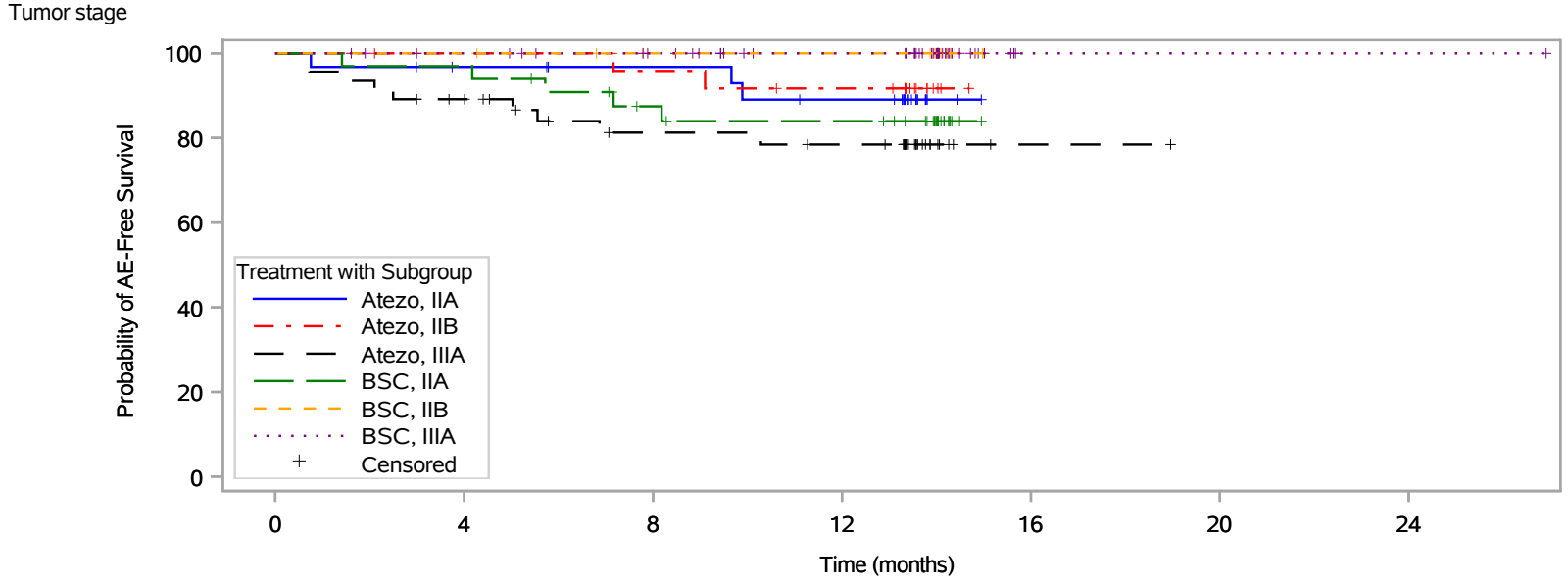
Verträglichkeit

Spezifische Verträglichkeit

KM Plots

Subgruppen

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
STUDY: GO29527



Patients at risk

Atezo, IIA	31	28	25	22	NE	NE	NE
Atezo, IIB	27	25	23	21	NE	NE	NE
Atezo, IIIA	46	38	29	27	1	NE	NE
BSC, IIA	33	32	25	23	NE	NE	NE
BSC, IIB	15	15	12	12	NE	NE	NE
BSC, IIIA	53	50	45	37	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: 26JAN2024

Program: ..al_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/g_km.sas
Output: ..E_DFS_FA/prod/output/g_km_sg_TTIMHP_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.pdf
30APR2024 23:21

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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

	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	
Category of Adverse Events Grade	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	0	0,0	1	4,0	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
Grade 1	15	14	93,3	0	0,0	0	0,0	0	0,0	0	0,0	1	6,7	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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
Serious Immune-Mediated Pneumonitis																														
All	2	1	50,0	0	0,0	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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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

Vollständige Darstellung relevanter Ergebnisse

	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	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
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

Includes adverse events occurring on or after the start of treatment in randomization period.
Clinical cut-off: 26JAN2024

Vollständige Darstellung relevanter Ergebnisse

	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	
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_DFS_FA/prod/output/t_ae_resolved_aesi_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 17:37

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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	Blood bilirubin increased	n/a	104	100,0	1	1,0	101	100,0	0	0,0
Investigations	Gamma-glutamyltransferase increased	n/a	104	100,0	1	1,0	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
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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)

Sex per eCRF

			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	Blood bilirubin increased	Male	82	78,8	1	1,2	71	70,3	0	0,0
Investigations	Blood bilirubin increased	Female	22	21,2	0	0,0	30	29,7	0	0,0
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	1	1,2	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:55

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)

Age at Randomization

			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	Blood bilirubin increased	< 65	64	61,5	1	1,6	62	61,4	0	0,0
Investigations	Blood bilirubin increased	>= 65	40	38,5	0	0,0	39	38,6	0	0,0
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	1	1,6	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:55

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)

Geographic 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	Blood bilirubin increased	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0,0
Investigations	Blood bilirubin increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0,0
Investigations	Blood bilirubin increased	North America	10	9,6	0	0,0	10	9,9	0	0,0
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:55

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)

Tumor stage per eCRF

			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	Blood bilirubin increased	IIA	31	29,8	0	0,0	33	32,7	0	0,0
Investigations	Blood bilirubin increased	IIB	27	26,0	0	0,0	15	14,9	0	0,0
Investigations	Blood bilirubin increased	IIIA	46	44,2	1	2,2	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	1	2,2	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

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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 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: 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	3	2,9	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
Investigations	Gamma-glutamyltransferase 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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:59

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)

Sex per eCRF

			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	2	2,4	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
Investigations	Gamma-glutamyltransferase increased	Male	82	78,8	1	1,2	71	70,3	0	0
Investigations	Gamma-glutamyltransferase increased	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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_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)

Age at Randomization

			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	2	3,1	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
Investigations	Gamma-glutamyltransferase increased	< 65	64	61,5	1	1,6	62	61,4	0	0
Investigations	Gamma-glutamyltransferase 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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:59

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)

Geographic 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	1	3,4	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
Investigations	Gamma-glutamyltransferase increased	Asia Pacific and Australia	29	27,9	1	3,4	23	22,8	0	0
Investigations	Gamma-glutamyltransferase increased	Europe and Middle East	65	62,5	0	0,0	68	67,3	0	0
Investigations	Gamma-glutamyltransferase 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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:59

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)

Tumor stage per eCRF

			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	3	6,5	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
Investigations	Gamma-glutamyltransferase increased	IIA	31	29,8	0	0,0	33	32,7	0	0
Investigations	Gamma-glutamyltransferase increased	IIB	27	26,0	0	0,0	15	14,9	0	0
Investigations	Gamma-glutamyltransferase 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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMH35_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
02MAY2024 10:59

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)

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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.x
02MAY2024 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: Immune-Mediated Hepatitis Serious
MODEL: Unstratified analysis
STUDY: GO29527
Dichotomous Analysis by Subgroups (Safety)

Sex per eCRF

			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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.x
02MAY2024 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: Immune-Mediated Hepatitis Serious
MODEL: Unstratified analysis
STUDY: GO29527
Dichotomous Analysis by Subgroups (Safety)

Age at Randomization

			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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.x
02MAY2024 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: Immune-Mediated Hepatitis Serious
MODEL: Unstratified analysis
STUDY: GO29527
Dichotomous Analysis by Subgroups (Safety)

Geographic 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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.x
02MAY2024 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: Immune-Mediated Hepatitis Serious
MODEL: Unstratified analysis
STUDY: GO29527
Dichotomous Analysis by Subgroups (Safety)

Tumor stage per eCRF

			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: 26JAN2024

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_FA/prod/output/t_ae_soc_descriptive_sg_IMHS_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.x
02MAY2024 11:02

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

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	21 (19.8%)	29 (28.2%)
Total number of treatments	55	80
ANTINEOPLASTIC AGENTS		
Total number of patients with at least one treatment	21 (19.8%)	29 (28.2%)
Total number of treatments	55	80
CARBOPLATIN	13 (12.3%)	11 (10.7%)
PEMBROLIZUMAB	4 (3.8%)	15 (14.6%)
CISPLATIN	4 (3.8%)	6 (5.8%)
DOCETAXEL	4 (3.8%)	6 (5.8%)
PEMETREXED	5 (4.7%)	5 (4.9%)
GEMCITABINE	5 (4.7%)	4 (3.9%)
PACLITAXEL	4 (3.8%)	3 (2.9%)
ETOPOSIDE	3 (2.8%)	1 (1.0%)
ATEZOLIZUMAB	0	3 (2.9%)
BEVACIZUMAB	0	3 (2.9%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	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%)

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%)
ANTINEOPLASTIC AGENTS	0	1 (1.0%)
B-RAF SERINE-THREONINE KINASE (BRAF) INHIBITORS	0	1 (1.0%)
CRIZOTINIB	1 (0.9%)	0
EPACADOSTAT	0	1 (1.0%)
MIRIPLATIN	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: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_cm_fu.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_cm_fu_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
06MAY2024 15:56

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Erste systemische Folgetherapie

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: First Subsequent Non-Protocol Anti-Cancer Therapy Regimen
MODEL: descriptive
STUDY: GO29527

	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)
Total number of patients with first subsequent non-protocol anti-cancer therapy regimen	21 (19.8%)	29 (28.2%)
CHEMOTHERAPY	16 (15.1%)	8 (7.8%)
CHEMOTHERAPY + IMMUNOTHERAPY	3 (2.8%)	4 (3.9%)
CHEMOTHERAPY + IMMUNOTHERAPY + TARGETED THERAPY, TKI	1 (0.9%)	0
CHEMOTHERAPY + TARGETED THERAPY, MONOCLONAL ANTIBODY	0	2 (1.9%)
CHEMOTHERAPY + TARGETED THERAPY, MONOCLONAL ANTIBODY + TARGETED THERAPY, TKI + UNKNOWN	0	1 (1.0%)
IMMUNOTHERAPY	0	13 (12.6%)
TARGETED THERAPY, TKI	1 (0.9%)	1 (1.0%)

Clinical cut-off: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_cm_fu_fr.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_cm_fu_fr_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
07MAY2024 9:30

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Bestrahlungstherapien

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Follow-up Radiotherapy
MODEL: descriptive
STUDY: GO29527

Location of Radiotherapy	Atezolizumab (N=106)	Best Supportive Care(BSC) (N=103)
Total number of patients with at least one radiotherapy	14 (13.2%)	24 (23.3%)
Total number of radiotherapies	15	32
BRAIN	2 (1.9%)	12 (11.7%)
LYMPH NODE	6 (5.7%)	5 (4.9%)
LUNG	5 (4.7%)	5 (4.9%)
BONE	2 (1.9%)	4 (3.9%)
OTHER	0	1 (1.0%)

Clinical cut-off: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_cm_rad.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_cm_rad_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
06MAY2024 16:00

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Operative Therapien

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIA Patients, SP263 TC >= 50%, Excluding Patients with EGFR/ALK Mutations
ENDPOINT: Follow-up 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	5 (4.7%)	10 (9.7%)	15 (7.2%)
Surgical procedure			
LOBECTOMY	0	1 (1.0%)	1 (0.5%)
OTHER	5 (4.7%)	9 (8.7%)	14 (6.7%)
Total number of surgeries	5	11	16
Location of surgery			
BRAIN	0	6 (54.5%)	6 (37.5%)
CHEST WALL	1 (20.0%)	0	1 (6.3%)
LUNG	3 (60.0%)	3 (27.3%)	6 (37.5%)
LYMPH NODE	0	1 (9.1%)	1 (6.3%)
OTHER	1 (20.0%)	1 (9.1%)	2 (12.5%)

Clinical cut-off: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_xp_fusurg.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_xp_fusurg_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
06MAY2024 16:04

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Lokalisation von Tumorrezidiven

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Intent-To-Treat Population, Disease Stage II-IIIA 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	11 (10.4%)	28 (27.2%)	39 (18.7%)
with CNS metastases	1 (0.9%)	11 (10.7%)	12 (5.7%)
Local Lung Cancer Recurrence	4 (3.8%)	8 (7.8%)	12 (5.7%)
Regional Lung Cancer Recurrence	12 (11.3%)	8 (7.8%)	20 (9.6%)
Second Primary Lung Cancer	1 (0.9%)	3 (2.9%)	4 (1.9%)
Total	28 (26.4%)	47 (45.6%)	75 (35.9%)

* identified in variable DFS.
Only counting CNS metastases present at date of first recurrence.
Percentages are based on N in the column headings.
Clinical cut-off: 26JAN2024

Program: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_Base/prod/program/t_recur2.sas
Output: root/clinical_studies/RO5541267/CDT30001/GO29527/data_analysis/ACE_DFS_FA/prod/output/t_recur2_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
28MAY2024 16:40

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Studienabbruch

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	72 (67.9%)	52 (50.5%)	124 (59.3%)
Alive: In Follow-Up	72 (67.9%)	52 (50.5%)	124 (59.3%)
Discontinued Study	34 (32.1%)	51 (49.5%)	85 (40.7%)
Death	22 (20.8%)	41 (39.8%)	63 (30.1%)
Lost to Follow-Up	0	1 (1.0%)	1 (0.5%)
Withdrawal by Subject	12 (11.3%)	8 (7.8%)	20 (9.6%)
Physician Decision	0	1 (1.0%)	1 (0.5%)

Clinical cut-off: 26JAN2024

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_FA/prod/output/t_ds_study_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
06MAY2024 15:34

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Behandlungsabbruch

Vollständige Darstellung relevanter Ergebnisse

POPULATION: Safety-Evaluable Population, Disease Stage II-IIIA 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: 26JAN2024

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_FA/prod/output/t_ds_trt_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
06MAY2024 15:32

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Follow-up Dauer

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)	62.82 (20.51)	53.92 (25.58)
Median	68,86	65,22
25% and 75%-ile	57.43 - 76.16	29.77 - 74.32
Min - Max	0.1 - 90.7	0.2 - 92.3

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: 26JAN2024

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_FA/prod/output/t_fu_FUEFF_EGFRALKNOUK_SP263T3_ST23_IT_26JAN2024_29527.xls
06MAY2024 15:46

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)	9.85 (3.58)	10.80 (3.26)
Median	11,33	12,02
25% and 75%-ile	11.09 - 11.65	11.10 - 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: 26JAN2024

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_FA/prod/output/t_fu_AER30_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
06MAY2024 15:47

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)	12.52 (3.61)
Median	13,31	13,96
25% and 75%-ile	12.96 - 13.62	13.08 - 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: 26JAN2024

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_FA/prod/output/t_fu_AER90_EGFRALKNOUK_SP263T3_ST23_SE_26JAN2024_29527.xls
06MAY2024 15:49

Endpunkte der Studie IMpower010

Aktueller Datenschnitt vom 26.01.2024

Sonstige Analysen

Anzahl Patienten mit Stadium IIIB

Anzahl Patienten mit Stadium IIIB

Stage per eCRF	Primary Tumor Stage	Regional Lymph Node Stage (pN)	UICC 8- T descriptor	RE-coding UICC 8-stage
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T2B	N2	T3	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	T3	N2	T4	STAGE IIIB
STAGE IIIA	TX	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
STAGE IIIA	T3	N2	cannot be recoded	potential STAGE IIIB
total number of patients in the label population:209			**stage IIIB (UICC 8) patients** **potential stage IIIB (UICC 8) patients**	**17/209 (8,1%)** **7/209 (3,3%)**
			maximum number of stage IIIB (UICC 8) patients	**24/209 (11,4%)**